NOTE

This Microfiche meets the quality requirements of the American National Standard for Microfiche of Documents (ANSI PH5.9-1975). However, because of imperfections in the document from which it was made, it contains images that are illegible or difficult to read. The source document for this microfiche is the best copy that could be obtained prior to filming.

CIS Congressional Information Service
Washington, D.C.

Calendar No. 646

101st Congress | 2d Session | SENATE | Report 101–338

THE TOBACCO PRODUCT EDUCATION AND HEALTH PROTECTION ACT

June 27 (legislative day, June 11), 1990.—Ordered to be printed

Mr. Kennedy, from the Committee on Labor and Human Resources, submitted the following

REPORT

[To accompany S. 2795]

The Committee on Labor and Human Resources, to which was referred the bill (S. 2795) having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

CONTENTS

		Page
I.	Summary of the bill	1
II.	Background	4
III.	Text of the bill as reported	8
IV.	Committee views	27
V.	History of the legislation	37
VI.	Committee action	37
VII.	Cost estimates	37
VIII.	Regulatory impact statement	39
IX.	Section-by-section analysis	40
X.	Changes in existing law	54

I. Summary of the Bill

As reported by the Committee, "The Tobacco Product Education and Health Protection Act" authorizes a new title XV of the Public Health Service Act to establish a program of information, education, and research regarding the hazards of tobacco use. Subtitle A of the new title XV establishes a Center for Tobacco Products to be headed by a Director appointed by the Secretary. The functions of the Secretary, through the Director, shall include public education and related activities on the health consequences of tobacco use; support of research efforts; assistance to States in enforcing State

S543-9

laws on the sale of tobacco products to minors; coordination of Federal education and research activities; documenting of additives contained in tobacco products, determining those that represent a health risk, and ensuring public disclosure of such information in such a manner that assures protection of proprietary information; and carrying out programs established under the new title XV.

The bill authorizes the Secretary, acting through the Center and in cooperation with non-Federal organizations, to carry out educational and research activities, including the preparation and distribution of materials, public service announcements, and educational campaigns; the provision of information to film makers, broadcast managers, and others regarding the role of the media in promoting tobacco use behavior; the conduct of research; the development of plans to provide outreach services to high risk groups and youth; and the conduct of reviews and research on the effectiveness of information contained on rotating warning labels.

Subtitle B of title XV as established by the bill authorizes support for various programs of grants, contracts, and cooperative agreements to be administered by the Center for public information campaigns including public service announcements, paid educational messages for print media, public transit advertising, and broadcast media. Such campaigns would focus on discouraging youth and others from initiating tobacco use, encouraging those who use tobacco products to stop, and messages to counter the current messages in tobacco advertisements that promote tobacco use.

The bill also authorizes model State leadership incentive grants for anti-tobacco use intervention. Such grants will be awarded to 10 to 20 States to assist them in meeting the costs of activities that will prevent the initial use of tobacco by minors, will encourage the cessation of tobacco use among youth and others, and will implement and enforce a prohibition on the sale of tobacco products to minors.

The bill authorizes education and demonstration grants, contracts, and cooperative agreements designed to decrease tobacco use in the workplace. Awards will be made to employer organizations, employer and employee consortia, and other organizations to help reduce the incidence of smoking and other tobacco use among workers with the highest prevalence of smoking.

The bill as approved by the Committee establishes a program to inform the public of the dangers to human health presented by cigarette smoking. The program will include research, public information and educational programs, coordination of activities, and other related activities on the effects of cigarette smoking and of passive smoke on human health. The bill provides for the establishment of an Interagency Committee on Smoking and Health to carry out these activities.

The bill also provides for the establishment of a program to inform the public of the dangers to human health resulting from the use of smokeless tobacco products, including the development and dissemination of educational programs and materials and public service announcements, the conducting and support of research and the collection, analysis, and dissemination of information on smokeless tobacco and health. This effort may also include technical assistance and grants to States to assist in developing and disseminating programs, materials, and announcements, and in assisting States in establishing 18 as the minimum age for the purchase of smokeless tobacco. The bill also mandates reports from the Secretary to the Congress on activities related to smokeless tobacco, including information on health education efforts, smokeless tobacco use, and an evaluation of the health effects of such use and the identification of areas for further research, as well as recommendations for legislation and administrative action.

Subtitle C of title XV as authorized by S. 1883 prohibits a number of acts related to the manufacture of tobacco products, including a manufacturer's failure to comply with provisions of the bill related to tobacco additives; the introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded; the adulteration or misbranding of a tobacco product in interstate commerce; the receipt of any tobacco product that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise; misuse or revealing of any method or process protected as a trade secret; misrepresentation of compliance with the provisions of title XV as authorized by the bill or any other Federal law or regulation; failure by a manufacturer to maintain copies of required materials; failure to make required reports, retain required records, and meet prescribed requirements under the title. The bill provides for the enforcement of these prohibitions through an Office of Regulatory Affairs and the U.S. district courts.

Chapter 2 of subtitle C of title XV as established by "The Tobacco Product Education and Health Protection Act" concerns misbranded and adulterated tobacco products. This chapter requires tobacco manufacturers, importers, and packagers to provide for the Secretary lists of tobacco additives used in manufacture, the range of quantities of such additives used, as well as information on the impact of such additives for health. If the Secretary determines that any tobacco additive significantly increases the risk to human health, the Secretary may require that levels of the additive be reduced or that it may be prohibited from use. The subtitle includes provisions for comment and judicial review for such determinations. The subtitle describes procedures for determining whether a tobacco product is misbranded or adulterated. The subtitle authorizes the Center to conduct examinations and investigations for the purposes of the title. Subtitle C, chapter 2, also provides that any product that contains nicotine but is not a tobacco product shall be considered to be a drug under the Federal Food, Drug, and Cosmetic Act.

The bill amends the Drug-Free Schools and Communities Act authorized by the 1986 Anti-Drug Abuse Act to include references to education on tobacco use along with that Act's focus on alcohol and drug abuse education. It also authorizes a program of incentive grants to State to be awarded by the Secretary of Education to help in the establishment of smoke-free schools.

The bill requires the Secretary of HHS, in consultation with the Secretary of Agriculture, to study and report to Congress on the use and effects of pesticides on tobacco and whether tolerances should be established for such use.

II. BACKGROUND AND NEED FOR THE LEGISLATION

> Cigarette smoking is the chief preventable cause of death in our society. It is directly responsible for some 390,000 deaths each year in the United States, or more than 1 of every 6 deaths in our country. The number of Americans who die each year from diseases caused by smoking exceeds the number of Americans who died in all of World War II, and this toll is repeated year after year.

These are the opening words of Smoking and Health: A National Status Report, a report to the Congress from the U.S. Department of Health and Human Services published in February 1990.

On May 10, 1990, the nation's newspapers reported on the preliminary results of a study by the Environmental Protection Agency on the risks of secondhand cigarette smoke, which tentatively concluded that passive smoking causes 3,000 or more lung cancer deaths annually and a substantial number of respiratory illnesses and deaths among the children of smokers.

On May 3, 1990, a Wall Street Journal headline—"With Help of Teens, Snuff Sales Revive"—led a story describing how, at the same time as cigarette sales are declining, consumption of moist snuff jumped 4.6 percent last year. The article went on to discuss how snuff products, "and the macho marketing pitches used to hawk them, hold an especially strong appeal for young people." The article cites a researcher, who says: "Kids start dipping at an earlier age than smoking. We're finding kids in elementary school using smokeless."

In 1988, cigarette advertising and promotional expenditures in the U.S. reached an all-time high of $3.27 billion—a 26.9 percent increase over 1987 expenditures of $2.58 billion. During the same period, the consumer price index (all items) increased 4.1 percent. From 1975 to 1988, total cigarette advertising and promotional expenditures increased more than sixfold: when adjusted by the consumer price index to constant 1975 dollars, cigarette advertising expenditures increased threefold. These data are from the April 27, 1990, issue of Morbidity and Mortality Weekly Report, a weekly periodical published by the Centers for Disease Control of the Department of Health and Human Services.

The preceding times, all published within a 2-month period in early 1990, indicate how much remains to be done in reducing the toll from the use of tobacco products. This struggle against preventable illness, disability, and death began nearly 30 years ago in 1962 when the Surgeon General of the Public Health Service appointed an advisory committee to study all published literature bearing on the relationship of smoking to health. After studying the problem for 18 months, the committee submitted the now-famous report to the Surgeon General on Janaury 11, 1964. The report contained the unanimous judgment of the Surgeon General's Advisory Committee on Smoking and Health that: "Cigarette smoking is a health hazard of sufficient importance in the United States to warrant remedial action." The report specifically linked cigarette smoking with the incidence of and mortality from lung cancer, chronic bronchitis and emphysema, and cardiovascular diseases.

The 1964 report of the Surgeon General's Advisory Committee gave impetus to two-and-half decades of legislation, administrative actions, and related activity to educate and inform the American public about the dangers of cigarette and other tobacco use. The first of these was the 1965 Federal Cigarette Labeling and Advertising Act, P.L. 89-92, which required each cigarette package to bear the warning: "Caution: Cigarette Smoking May Be Hazardous to Your Health." In addition to this initial legislative activity, other actions were taken by the Federal Government and by the private sector. The Public Health Service developed and disseminated programs for the public as well as for health care professionals on smoking education and also established a national clearinghouse on smoking and health information. In addition, State and local health and education authorities and the major voluntary health organizations, launched vigorous smoking education programs.

The next landmark in the history of Federal action on tobacco use and health came in 1969 and 1970 when the 91st Congress considered and passed legislation relating to cigarette labeling, and advertising as well. The Public Health Cigarette Smoking Act of 1970, P.L. 91-222:

> Changed the cigarette package label wording to "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health"; and
>
> Prohibited advertising of cigarettes on radio and television beginning January 2, 1971.

The 1970 Act also required annual reports to Congress on the health consequences of smoking—the Surgeon General's annual reports, which have in the years since made an important contribution to the body of scientific knowledge.

In August of 1970, the Federal Trade Commission issued a proposed rule to require cigarette manufacturers to disclose tar and nicotine content of cigarettes in their print advertising. The proceeding was suspended in December of that year when cigarette manufacturers agreed voluntarily to make the disclosures. By December 1971, all cigarette advertisements included tar and nicotine content information.

The Health Services and Centers Amendments of 1978, P.L. 95-626, directed the Secretary to conduct a "study of studies of (1) the relative health risks associated with smoking cigarettes of varying levels of tar, nicotine, and carbon monoxide; and (2) the health risks associated with smoking cigarettes containing any substance commonly added to commercially manufactured cigarettes." The 1981 report of the Surgeon General, subtitled "The Changing Cigarette," addressed the issue of the potential hazards of substances added to cigarettes. One of the report's basic findings questioned the use of additives—"whether the new cigarettes being produced today introduced new risks through their design, filtering mechanisms, tobacco ingredients, or additives," and noted that it was not possible "to assess the relative risks of cigarette additives because information was not available from manufacturers as to what these additives are." The 1981 report recommended that "flavoring agents and additives should be studied * * * for carcinogenicity and toxicity before their commercial use is permitted, and the results of such studies should be made available."

Also in 1981 the Federal Trade Commission (FTC) published a staff report on an investigation of cigarette advertising which found that past efforts of the Commission, the Congress, and other Government agencies and private organizations had had a significant impact in informing the public on the hazards of smoking but that problems still existed. It found, for instance, that while most Americans were aware generally of the dangers of smoking, some consumers did not have enough information about the health risks of smoking to know how dangerous smoking is, i.e., what is the nature and extent of the health risks of smoking. The FTC report indicated that many Americans still did not know that specific diseases where related to smoking. For example, the report cited polls showing that over 30 percent of the public was unaware of the relationship between smoking and heart disease. Nearly 50 percent of all women did not know that smoking during pregnancy increases the risk of stillbirth and miscarriage. Even for lung cancer, which was the first and is probably the best-known, disease associated with smoking, it was clear that gaps still existed in consumer knowledge about smoking—20 percent of those polled did not know that smoking causes cancer.

The Comprehensive Smoking Education Act of 1984, P.L. 98-474, stepped up the national campaign to increase the availability of information on the health consequences of smoking. It gave the Secretary broad authority in the areas of research, education, and information to inform the public of any dangers to human health presented by cigarette smoking. It authorized the establishment of an Interagency Committee on Smoking and Health to coordinate research and educational programs and activities and establish and maintain liaison with private entities, other Federal agencies, and State and local agencies concerning activities relating to smoking and health.

The 1984 legislation also changed the system of warning labels on cigarette packages and in cigarette advertising, instituting a rotating system utilizing four different specific informational labels:

Surgeon General's Warning: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy;

Surgeon General's Warning: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health;

Surgeon General's Warning: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight;

Surgeon General's Warning: Cigarette Smoke Contains Carbon Monoxide.

The 1984 Comprehensive Smoking Education Act also included provision to require cigarette manufacturers, packagers, and importers to provide the Secretary with a list of ingredients added to tobacco in the manufacture of cigarettes and to direct the Secretary to report to Congress on research on the health effects of ingredients, and on information pertaining to any such ingredient which poses a health risk to smokers.

The Comprehensive Smokeless Tobacco Health Education Act of 1986, P.L. 99-252 was the response of the Congress to its concern about reported increases in the use of smokeless tobacco products, particularly among young men. The Act authorized the establishment of a public education program about the dangers to health from the use of smokeless tobacco. It also required three warning labels to be used on packages and in advertising for smokeless tobacco products:

Warning: This Product May Cause Mouth Cancer;

Warning: This Product May Cause Gum Disease and Tooth Loss; and

Warning: This Product Is Not a Safe Alternative to Cigarettes.

The 1986 legislation also instituted ingredient reporting requirements for smokeless products similar to those established in the 1984 Comprehensive Smoking Education Act for cigarettes.

Despite all that Congress, the Department of HHS, State and local agencies, and national organizations have done to spread the word about the hazards of tobacco use, it remains public health enemy number 1 in America today. As noted above, tobacco use is the leading preventable cause of death. Smoking causes 87 percent of lung cancer and 33 percent of all cancers. It causes 40 percent of heart disease, 18 percent of strokes, and 10 percent of infant mortality.

The ominous part of the tobacco use problem is that it starts so early and is so difficult to stop. An estimated 90 percent of all smokers begin between the ages of 15 and 19, 25 percent between 12 and 14, and 25 percent before age 12. By high school graduation, 53 percent of students who smoke half a pack a day have tried to stop and found that they couldn't. Adult smokers have just as much difficulty quitting once they have become addicted. Eighty percent of current smokers have expressed a desire to stop—but two-thirds have made a serious effort and failed.

Cigarettes are not the only tobacco product in popular use; many young people, boys in particular, have taken to the use of smokeless tobacco products in the mistaken belief that they are not as hazardous to health as cigarettes, and have helped boost the sales of such products, as noted above.

The success of tobacco product advertising in the face of the facts is undeniable. Cigarettes remain one of the most heavily advertised products in the print media. In 1988, FTC data indicate that cigarettes were the most heavily advertised product in outdoor media, the second most heavily advertised product in magazines (after passenger cars), and the sixth most heavily advertised product in newspapers. When advertising expenditures of these three media are combined, cigarettes are the second most heavily advertised product overall (after passsenger cars.)

Tobacco product advertising and promotion may increase cigarette consumption by (1) encouraging children and adolescents to experiment with and initiate regular use of cigarettes and other tobacco products; (2) deterring current smokers and other tobacco product users from quitting; (3) prompting former smokers to start again; and (4) increasing smokers' daily cigarette consumption by serving as an external cue to smoke. The ubiquity of advertising for cigarettes and other tobacco products may contribute to the perception that smoking and other tobacco use is less hazardous, more prevalent, and more socially acceptable than it is. Advertising campaigns for cigarettes and other tobacco products increasingly focus on groups that account for a growing percentage of the smoking and tobacco use population—women, minorities, and blue-collar workers.

III. Text of the Bill as Reported

[S. 2795, 101st Cong., 2d Sess.]

A BILL To amend the Public Health Service Act to establish a center for tobacco products, to inform the public concerning the hazards of tobacco use, to provide for disclosure of additives to such products, and to require that information be provided concerning such products to the public, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Tobacco Product Education and Health Protection Act of 1990".

SEC. 2. FINDINGS AND PURPOSES.

(a) Findings.—Congress finds that—

(1) despite a steady decline in tobacco consumption, 52,000,000 Americans still use tobacco products annually;

(2) tobacco use causes nearly 400,000 deaths each year in the United States, the equivalent of over 1,000 deaths a day;

(3) tobacco use is the most important cause of death and illness in the United States today, causing one sixth of all deaths annually;

(4) in 1985, the private and public sectors in the United States spent approximately $22,000,000,000 on smoking-related illnesses and absorbed $43,000,000,000 in economic losses from such illnesses;

(5) 50 percent of all smokers begin using tobacco by the age of 14, and 90 percent of all smokers begin using tobacco before the age of 20;

(6) tobacco products contain nicotine and are addictive;

(7) most young people initiate tobacco use and become addicted before they are sufficiently informed or mature enough to make an informed choice concerning such use;

(8) the tobacco industry contributes significantly to the experimentation with tobacco and the initiation of regular tobacco use by children and young adults through its advertising and promotion practices;

(9) in 1988 the tobacco industry spent $3,250,000,000 on the advertising and promotion of tobacco products, ranking such products among the most heavily advertised and promoted products in the United States;

(10) the tobacco industry claims that the purpose of advertising is to influence consumer brand selection, but only 10 percent of tobacco users switch brands each year;

(11) convincing evidence demonstrates that tobacco advertising is predominantly directed at market expansion or retention or both;

(12) the tobacco industry must attract 6,000 new smokers daily to replace those who stop smoking or who die of smoking-related diseases and other causes, or who quit;

(13) tobacco product advertising and promotion are intended to capture the youth market and seek to do so through advertisements that suggest a strong association between smoking and physical fitness, attractiveness, success, adventure, and independence, and advertisements that are designed to influence minors, who are more vulnerable to image-based advertising;

(14) serious gaps in knowledge about the harmful effects of the use of tobacco products persist in both minors and the adult population, with surveys showing that large numbers of citizens are unaware that smoking causes lung cancer, heart disease and still births in pregnancy;

(15) education is effective in preventing and halting the use of tobacco products;

(16) the proportion of smokers among the most educated adults is less than half that among the least educated adults;

(17) the highest percentage of smoking is among those individuals with the least amount of education, including young citizens, blue-collar workers, high school drop-outs and minorities;

(18) the total resources of the major voluntary organizations that sponsor educational activities on smoking have never exceeded 2 percent of tobacco industry expenditures for the promotion of tobacco;

(19) children and teenagers should be informed about the dangers of smoking and be discouraged from initiating the use of tobacco products;

(20) the American public and groups with high prevalences of tobacco use should be informed about the dangers of tobacco products;

(21) although most States prohibit the sale of tobacco products to minors, such laws are not uniformly enforced;

(22) in recent years, there have been efforts in some States to improve the enforcement of existing laws which prohibit the sale of tobacco products to minors;

(23) cooperative Federal-State efforts will encourage more effective action to limit the sale of tobacco products to minors;

(24) no Federal law currently requires public disclosure of the numerous additives in tobacco products; and

(25) tobacco and tobacco products are in interstate commerce.

(b) Purposes.—It is the purpose of this Act to—

(1) help educate citizens to prevent initiation and encourage cessation of tobacco use;

(2) inform the public about the harmful effects of tobacco products;

(3) support State efforts to improve educational programs for the prevention and cessation of tobacco use;

(4) support State efforts to strengthen laws limiting the sale of tobacco products to minors;

(5) provide for the determination of the risk to individual health of additives to tobacco products and establish Federal regulatory authority over such additives; and

(6) ensure the disclosure of accurate information to the public.

SEC. 3. TOBACCO HEALTH AND EDUCATION PROGRAMS.

The Public Health Service Act is amended by inserting before title XVI (42 U.S.C. 300q et seq.) the following new title:

"TITLE XV—TOBACCO HEALTH AND EDUCATION PROGRAMS

"Subtitle A—Center for Tobacco Products

"SEC. 1501. ESTABLISHMENT OF CENTER.

"(a) IN GENERAL.—The Secretary shall establish a Center for Tobacco Products that shall be headed by a Director, who shall be appointed by the Secretary.

"(b) FUNCTIONS.—The Secretary, acting through the Director of the Center shall—

"(1) educate the public concerning the health consequences of using tobacco products, provide outreach services to youth, and promote cessation of tobacco use through the provision of technical and material assistance to States, workplaces, and the media;

"(2) support research efforts concerning patterns of tobacco use and cessation;

"(3) provide assistance to States to enhance their efforts to enforce existing State laws concerning the sale of tobacco products to minors within the State;

"(4) coordinate the education and research activities of the Federal Government with regard to tobacco products;

"(5) document the additives that are contained in tobacco products, determine the additives that represent a health risk, restrict the use of tobacco additives that represent a significant additional health risk to the public, and ensure the disclosure of such information to the public in a manner that assures the protection of proprietary information; and

"(6) carry out the programs established under this title.

"(c) CONTRACTS.—The Secretary, acting through the Director of the Center, may enter into contracts and cooperative agreements with Federal agencies within and outside of the Public Health Service in the exercise of the functions of the Secretary under this title.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $25,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

"SEC. 1502. EDUCATIONAL AND RESEARCH ACTIVITIES.

"The Secretary, acting through the Director of the Center and in cooperation with non-Federal entities, shall carry out educational and research activities that shall include—

"(1) the preparation and distribution of materials to educate the public concerning the health effects of using tobacco products;

"(2) the preparation of public service announcements and the preparation and implementation of educational campaigns (that include paid advertising) to inform specific populations, including youth and the general population, of the health effects of using tobacco products and the opportunities for prevention and cessation of such use;

"(3) the provision of information to film makers, broadcast media managers, and others regarding the role of the media in promoting tobacco use;

"(4) the conduct of research on patterns of tobacco use, initiation, and cessation, and effective methods for disseminating such information;

"(5) the development of plans to effectively provide outreach services to high risk groups and youth with such information; and

"(6) the conduct of reviews of the effectiveness of information required to be contained in rotating warning labels on tobacco product packages and the undertaking of research to establish how to improve the effectiveness of such labels.

"Subtitle B—Anti-Smoking Programs

"CHAPTER 1—PUBLIC INFORMATION CAMPAIGNS

"SEC. 1511. GRANTS FOR PUBLIC INFORMATION CAMPAIGNS.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Center, shall make grants to public or nonprofit private entities, or enter into contracts or cooperative agreements with private entities, to conduct public information campaigns concerning the use of tobacco products.

"(b) ACTIVITIES.—Assistance under this chapter shall be used for the development of a public information campaign that may include public service announcements, paid educational messages for print media, public transit advertising, electronic broadcast media, and any other mode of conveying information concerning tobacco products that the Secretary considers appropriate. Such activities shall—

"(1) focus on seeking to discourage the initiation of use of tobacco products by youth and nonusers;

"(2) encourage cessation of tobacco use by those who currently use tobacco products; and

"(3) counter the messages contained in tobacco advertisements that promote tobacco use.

Such activities shall focus on one or more of the specific groups described in subsection (c)(1).

"(c) CRITERIA.—The Secretary, acting through the Director of the Center, shall publish the criteria used for awarding grants under this chapter in the Federal Register. Such criteria shall ensure that the applicant—

"(1) will conduct activities that educate one or more communities or groups with high prevalences of tobacco use and high health risks from tobacco use, specifically youth, school dropouts, pregnant women, minorities, blue collar workers, and low income individuals;

"(2) has a record of high quality campaigns of a comparable type; and

"(3) has a record of high quality campaigns that educate the population groups specified in paragraph (1).

"(d) PREFERENCE.—

"(1) IN GENERAL.—In awarding grants, contracts, or agreements under this chapter, the Secretary shall give a preference to those applicants that will conduct activities that will most likely encompass an audience that includes several of the groups identified in subsection (c)(1).

"(2) COMPREHENSIVENESS.—In awarding grants, contracts, or agreements under this chapter, the Secretary shall attempt to distribute such grants, contracts, or agreements so that all groups identified in subsection (c)(1) are reached with diverse media. Single grants, contracts, or agreements shall not require that all groups are reached or that all media must be used.

"SEC. 1512. GRANT APPLICATION.

"(a) REQUIREMENT.—No grant, contract, or cooperative agreement shall be made or entered into under this chapter unless an application that meets the requirements of subsection (b) has been submitted to, and approved by, the Secretary.

"(b) CONTENTS.—An application submitted under subsection (a) shall provide such agreements, assurances, and information, be in such form and submitted in such manner as the Secretary shall prescribe through notice in the Federal Register. Such application shall contain—

"(1) a complete description of the plan of the applicant for the development of a public information campaign, including—

"(A) an identification of the specific audiences that shall be educated by the campaign, including one or more communities or groups with high prevalences of tobacco use and high health risks from tobacco use, such as youth, school dropouts, minorities, blue collar workers, pregnant women, and low income individuals;

"(B) an identification of the media to be used in the campaign and the geographic distribution of the campaign;

"(C) a description of plans to test market the campaign with a relevant population group and in a relevant geographic area; and

"(D) an assurance that effectiveness criteria will be implemented prior to the completion of the final plan that shall include an evaluation component to measure the overall effectiveness of the campaign; and

"(2) a complete description of the kind, amount, distribution, and timing of informational messages and an assurance that the applicant will work with any media organizations or other groups with which such messages are placed to ensure that such organizations or groups will not lower the current frequency of public service announcements.

"SEC. 1513. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to make grants or enter into contracts or agreements under this chapter, $50,000,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 and 1993.

"CHAPTER 2—MODEL STATE LEADERSHIP INCENTIVE GRANTS FOR ANTI-TOBACCO USE INTERVENTION

"SEC. 1515. GRANT PROGRAM.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Center, shall designate not less than 10 nor more than 20 States as model States under subsection (b), and shall make grants to each designated model State to assist the State in meeting the costs of improving State leadership concerning activities that—

"(1) will prevent the initial use of tobacco products by minors;

"(2) will encourage the cessation of the use of tobacco products among the youth and other residents of the State, with particular attention directed towards those individuals and groups who are at high risk and suffer high prevalences of tobacco use, including school dropouts, minorities, low-income individuals, pregnant women and blue collar workers; and

"(3) will implement and enforce a prohibition on the sale of tobacco products to minors.

"(b) CRITERIA FOR MODEL STATE DESIGNATION.—To be designated as a model State under subsection (a), a State shall—

"(1) have in effect a law that prohibits the sale of tobacco products to individuals under the age of 18;

"(2) seek to improve the enforcement of the law referred to in paragraph (1);

"(3) have in effect a law or regulation that is intended to reduce the use of, or access to, cigarette vending machines by minors who are under the age of 18; and

"(4) seek to improve the enforcement of the law or regulation referred to in paragraph (3).

"SEC. 1516. APPLICATIONS.

"To be eligible to be designated as a model State under section 1515 and receive a grant, a State shall prepare and submit to the Secretary an application that—

"(1) includes a designation of a lead agency within the State that will work in conjunction with the Center, and contain assurances that such agency—

"(A) has experience in matters that affect the public health;

"(B) has expertise regarding the health effects and use of tobacco products;

"(C) provides direct services for smoking cessation or referrals for such services;

"(D) administers activities intended to prevent the initiation of use of tobacco products by minors who are under the age of 18, and by other individuals;

"(E) will have a lead office or division that will have the experience and expertise described in subparagraphs (A) and (B) and will be chiefly responsible for the functions described in subparagraphs (C) and (D); and

"(F) will provide personnel sufficient to staff the lead office or division;

"(2) provides assurances that as part of a program to improve State enforcement of laws prohibiting the sale of tobacco products to minors the State, will—

"(A) establish a mechanism for the reporting of citizen or other complaints to the office or division referred to in paragraph (1)(E) concerning retail establishments that sell tobacco products to minors in violation of State law;

"(B) establish a program to make the public aware of the office or division referred to in paragraph (1)(E);

"(C) establish a procedure by which the State may make a finding or a presumption that a retail establishment has a pattern or practice of selling tobacco products to minors in violation of State law; and

"(D) establish a procedure for the lead State agency to report periodically to the Center regarding the implementation of subparagraphs (A) through (C);

"(3) includes a complete description of the type of programs that will be established or assisted by or through the State, and a statement of goals, objectives, and timetables of such programs or activities that are consistent with the purposes of section 1515;

"(4) specifies how the State will meet the criteria described in section 1517;

"(5) includes copies of the State laws and regulations described in paragraphs (1) and (3) of section 1515(b); and

"(6) is in such form, is submitted in such manner, and contains such information as the Secretary shall require, including such other information as the Secretary may by regulation prescribe.

"SEC. 1517. GRANT CRITERIA.

"The Secretary, acting through the Director of the Center, shall establish criteria for awarding grants under this chapter. Such criteria shall include requirements that the State must provide—

"(1) evidence that the State has made efforts to discourage tobacco use among the youth residing in such State;

"(2) evidence of the need of the State for the assistance that is requested, as reflected in the prevalence of the use of tobacco within the State, especially among the populations that are described under section 1515(a)(2), and assurances that the State intends to concentrate its efforts on such populations; and

"(3) evidence of the need of the State for the assistance that is requested, as reflected in the necessity for the development of statewide expertise in the planning of, and implementation of anti-tobacco use interventions;

"(4) evidence of cooperative arrangements that the State has, or will enter into, with other entities that will participate in the activities established or assisted under the grant.

"SEC. 1518. ASSISTANCE TO MODEL STATES.

"The Secretary, acting through the Director of the Center, shall provide to designated model States, on request—

"(1) model printed materials for distribution to retail establishments concerning the health hazards and illegality of the sale of tobacco products to minors;

"(2) support for, and assistance in, the planning of meetings, conferences, and conventions to educate retail establishments concerning the health hazards associated with tobacco products, the addictive nature of tobacco products, and State laws that prohibit the sale of tobacco products to minors;

"(3) technical assistance in the development of reporting systems to identify specific retail establishments and retail chains that consistently sell tobacco products to minors in violation of State law;

"(4) assistance in the development of notification systems to make specific retail establishments aware that such establishments are acting consistently in violation of State law; and

"(5) model notices to be distributed to retail establishments concerning the awareness of State authorities and of the Center of the continued sale by the establishment of tobacco products to minors in violation of State law.

"SEC. 1519. AUTHORIZATION OF APPROPRIATIONS.

"(a) IN GENERAL.--There are authorized to be appropriated to make grants under this chapter, $25,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

"(b) DISTRIBUTION OF FUNDS.—Funds shall be distributed under this chapter so that no State designated by the Secretary as a model State shall receive more than $2,000,000 for each fiscal year under this section.

"CHAPTER 3—EDUCATION TO DECREASE TOBACCO USE IN THE WORKPLACE

"SEC. 1521. PURPOSE.

"The Secretary, acting through the Center, shall make grants to public and nonprofit entities and enter into contracts and cooperative agreements with private entities (including employer organizations and employer and employee consortia) for educational activities to reduce the incidence of tobacco use among workers with high prevalences of tobacco use. Such grants, contracts, or cooperative agreements shall be used for meeting all or part of the costs of activities that will prevent the initiation, and encourage the cessation, of the use of tobacco products among workers and their families. In making grants and entering into contracts and cooperative agreements, the Secretary shall give priority to applicants that will educate groups with the highest prevalences of tobacco use.

"SEC. 1522. ACTIVITIES AND CRITERIA.

"(a) Activities.—Assistance provided under this chapter shall be used for—

"(1) education to promote the cessation of tobacco use among workers who have high prevalences of tobacco use;

"(2) information and activities to provide family members of workers with education concerning the health consequences of tobacco use;

"(3) training and education to develop the expertise of a health educator or other personnel who will perform the activities described in this subsection for workers and their families; and

"(4) the development of audio, visual, or print materials that will facilitate any of the activities described in this subsection when such appropriate audio, visual, or print materials are not otherwise available.

"(b) Criteria.—The Secretary, acting through the Director of the Center, shall establish criteria for the awarding of grants under this chapter that shall include requirements that the applicant provide to the Secretary, in the application required under section 1523—

"(1) evidence of—

"(A) the potential for success of the proposed plan of the applicant; and

"(B) the existence of any cooperative arrangements with other entities that will participate in the proposed plan;

"(2) an agreement that activities to be conducted under the grant will be implemented with the cooperation of the employer; and

"(3) any other information as the Secretary shall specify.

"SEC. 1523. APPLICATION.

"(a) Requirement.—No grant, contract or cooperative agreement shall be made under this chapter unless an application therefor has been submitted to, and approved by, the Secretary.

"(b) Contents.—An application submitted under subsection (a) shall be in such form and submitted in such manner as the Secretary shall prescribe through publication of a notice in the Federal Register. Such application shall contain—

"(1) a complete description of the type of educational activities that the applicant intends to carry out with assistance provided under this chapter, including—

"(A) a description of the activities that are designed to establish an ongoing anti-tobacco program that may include working cooperatively with existing anti-tobacco programs in the community or State; and

"(B) an assurance that activities conducted under subparagraph (A) will demonstrate a concentration of effort to change tobacco use behavior in those groups identified in section 1521 and will include one or more of the activities described in section 1522;

"(2) an assurance by the applicant of its ongoing commitments to support the anti-tobacco use activities after the period of the grant, contract, or cooperative agreement has expired;

"(3) a description of the manner in which the applicant will meet the criteria specified in section 1522; and

"(4) such other information as the Secretary may by regulation prescribe.

"SEC. 1524. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to make grants, contracts, or agreements under this chapter, $5,000,000 for each of the fiscal years 1991 through 1993.

"CHAPTER 4—INFORMATION REGARDING CIGARETTE SMOKING

"SEC. 1526. DEFINITIONS.

"As used in this chapter:

"(1) COMMITTEE.—The term 'Committee' means the committee established under section 1527(c), or the committee established under section 3(b) of the Comprehensive Smoking Education Act (15 U.S.C. 1341(b)) as such section existed before the date of enactment of this section.

"(2) UNITED STATES.—The term 'United States', when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Island, and the installations of the Armed Forces.

"SEC. 1527. SMOKING RESEARCH, EDUCATION, AND INFORMATION IN GENERAL.

"(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish and carry out a program to inform the public of the dangers to human health presented by cigarette smoking.

"(b) ADMINISTRATION OF PROGRAM.—In carrying out the program established under subsection (a), the Secretary shall—

"(1) conduct and support research on the effects of cigarette smoking and of passive smoke on human health and develop materials for informing the public of such effects;

"(2) coordinate all research and educational programs and other activities within the Department of Health and Human Services that relate to the effect of cigarette smoking and passive smoke on human health and coordinate, through the Committee, with similar activities of other Federal agencies and of private agencies;

"(3) establish and maintain liaison with appropriate private entities, other Federal agencies, and State and local public agencies concerning activities relating to the effect of cigarette smoking and passive smoke on human health;

"(4) collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking and passive smoke on human health, and develop standards, criteria, and methodologies to improve information programs related to smoking and health;

"(5) compile and make available information on State and local laws relating to the use and consumption of cigarettes;

"(6) establish an outreach program to inform individuals under the age of 18 about the health consequences of smoking; and

"(7) undertake any other additional information and research activities that the Secretary determines necessary and appropriate to carry out this section.

"(c) COMMITTEE.—

"(1) ESTABLISHMENT.—To carry out the activities described in paragraphs (2) and (3) of subsection (b), the Secretary shall establish an Interagency Committee on Smoking and Health.

"(2) COMPOSITION.—The Committee established under paragraph (1) shall be composed of—

"(A) the Director of the Center;

"(B) members appointed by the Secretary from appropriate institutes and agencies of the Department, that may include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, Health Resources and Services Administration, and the Centers for Disease Control;

"(C) one member appointed from each of the Federal Trade Commission, the Department of Education, the Department of Labor, and any other Federal agency designated by the Secretary, the appointment of whom shall be made by the head of the entity from which the member is appointed; and

"(D) five members appointed by the Secretary from physicians and scientists who represent private entities involved in informing the public about the health effects of tobacco use and passive smoking.

"(3) CHAIRPERSON.—The Secretary shall designate the chairperson of the Committee established under paragraph (1).

"(4) EXPENSES.—While away from their homes or regular places of business in the performance of services for the Committee established under paragraph (1), members of such Committee shall be allowed travel expenses, including per diem in lieu of subsistence, in the manner provided by sections 5702 and 5703 of title 5 of the United States Code.

"(5) OTHER INFORMATION.—The Secretary shall make available to the Committee established under paragraph (1) such staff, information, and other assistance as it may require to carry out its activities effectively.

"(d) REPORT.—Not later than January 1, 1991, and biennially thereafter, the Secretary shall prepare and submit, to the appropriate Committees of Congress, a report that shall contain—

"(1) an overview and assessment of Federal activities undertaken to inform the public of the health consequences of smoking and passive smoke and the extent of public knowledge of such consequences;

"(2) a description of the activities of the Secretary and the Committee under subsection (a);

"(3) information regarding the activities of the private sector taken to deal with the effects of smoking on health; and

"(4) such recommendations as the Secretary may consider appropriate.

"SEC. 1528. PUBLIC EDUCATION REGARDING SMOKELESS TOBACCO.

"(a) Development.—

"(1) In general.—The Secretary, acting through the Director of the Center, shall establish and carry out a program to inform the public of dangers to human health resulting from the use of smokeless tobacco products.

"(2) Duties of secretary.—In carrying out the program established under paragraph (1) the Secretary, acting through the Director of the Center, shall—

"(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

"(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this section;

"(C) conduct and support research concerning the effects of the use of smokeless tobacco on health; and

"(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

"(3) Consultation.—In developing programs, materials, and announcements under paragraph (2), the Secretary shall consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

"(b) Assistance.—The Secretary may provide technical assistance and make grants to States—

"(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

"(2) to assist in the distribution of such programs, materials, and announcements through the States; and

"(3) to assist States in enacting laws and regulations to establish 18 as the minimum age for the purchase of smokeless tobacco.

"SEC. 1529. REPORTS.

"Not later than January 1, 1991, and biennially thereafter, the Secretary shall prepare and submit, to the appropriate Committees of Congress, a report containing—

"(1) a description of the effects of health education efforts on the use of smokeless tobacco products;

"(2) a description of the use by the public of smokeless tobacco products;

"(3) an evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research; and

"(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

"CHAPTER 5—GENERAL PROVISIONS

"SEC. 1535. ADMINISTRATIVE PROVISIONS.

"(a) Amount and Method of Payment.—

"(1) Amount.—The Secretary shall determine the amount of a grant, contract, or agreement awarded under this subtitle.

"(2) Method.—Payments under grants, contracts, or cooperative agreements awarded under this subtitle may be made in advance, on the basis of estimates, or by way of reimbursement, with necessary adjustments because of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary determines necessary to carry out the purposes of such grants, contracts, or agreements.

"(b) Maintenance of Effort.—No grant, contract, or agreement shall be made under this subtitle unless the Secretary determines that there is satisfactory assurance that Federal funds made available under such a grant, contract, or agreement for any period will be so used as to supplement and, to the extent practical, increase the level of State, local, and other non-Federal funds that would, in the absence of such Federal funds, be made available for the program for which the grant, contract, or agreement is to be made and will in no event supplant such State, local and other non-Federal funds.

"(c) Supplies, Equipment, and Employee Detail.—

"(1) In general.—The Secretary, at the request of a recipient of a grant, contract, or cooperative agreement under this subtitle, may reduce the amount of such a grant, contract, or agreement by—

"(A) the fair market value of any supplies or equipment furnished to the recipient by the Secretary;

"(B) the amount of pay, allowances. and travel expenses incurred by any officer or employee of the Federal government when such officer or employee has been detailed to the recipient; and

"(C) the amount of any other costs incurred in connection with the detail of an officer or employee as described in subparagraph (B);

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience, and at the request, of such recipient and for the purpose of carrying out activities under the grant, contract, or agreement.

"(2) Use of amount of reduction.—The amount by which any grant, contract, or agreement awarded under this subtitle is reduced under this subsection shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant, contract, or agreement is based, and such amount shall be considered as part of the grant, contract, or agreement that has been paid to the recipient.

"(d) Records.—Each recipient of a grant, contract, or agreement under this subtitle shall keep such records as the Secretary determines appropriate, including records that fully disclose—

"(1) the amount and disposition by such recipient of the proceeds of such grant contract, or agreement;

"(2) the total cost of the activity for which such grant, contract, or agreement was made;

"(3) the amount of the cost of the activity for which such grant, contract, or agreement was made that has been received from other sources; and

"(4) such other records as will facilitate an effective audit.

"(e) Audit and Examination of Records.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a grant, contract, or cooperative agreement under this subtitle, for the purpose of conducting audits and examinations of such recipient that are pertinent to such grant, contract, or agreement.

"Subtitle C—Prohibited Acts, Enforcement, and Additives

"CHAPTER 1—PROHIBITED ACTS AND ENFORCEMENT

"SEC. 1541. PROHIBITED ACTS.

"(a) In General.—The following acts and the causing thereof are prohibited:

"(1) Compliance.—The failure of a manufacturer of a tobacco product to comply with section 1551.

"(2) Delivery.—The introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded.

"(3) Adulteration or misbranding of product in commerce.—The adulteration or misbranding of any tobacco product in interstate commerce.

"(4) Receipt.—The receipt in interstate commerce of any tobacco product that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

"(5) Trade secret.—The using by any person to the advantage of such person, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this title, any information acquired under authority of this title concerning any method or process that as a trade secret is entitled to protection. This paragraph shall not be construed to prohibit disclosure of information to Congress.

"(6) Misrepresentation of approval.—The representation or suggestion that an approval of any tobacco product is in effect under this title or any other Federal law or regulation.

"(7) Copies of material.—The failure of the manufacturer of a tobacco product to maintain for transmittal, or to transmit, to any individual who makes a written request for information as to such product, true and correct copies of all printed matter that are required to be included in or on any package of a tobacco product.

"(8) Reports, records, requirements.—The failure to make reports required, the failure to retain records required, or the failure to meet requirements prescribed, under this title.

"(b) Office of Regulatory Affairs.—To carry out this subtitle, the Secretary shall establish within the Public Health Service, or designate an existing entity within such Service as, an Office of Regulatory Affairs. Such office shall coordinate its work with other offices and agencies of the Federal Government.

"SEC. 1542. ENFORCEMENT.

"(a) In General.—Any person who violates the provisions of this subtitle shall be subject to the penalties described in subsection (b).

"(b) Jurisdiction.—The district courts of the United States shall have jurisdiction over violations of section 1541 in the same manner, and may enforce the same and take the same actions, as described under sections 302, 303(a), 303(c)(1), 303(c)(2), 304(a)(1), 304(b), 304(c), 304(d), 304(e), 304(f), 306, and 307 of the Federal Food, Drug, and Cosmetic Act with respect to violations of section 301 of such Act (20 U.S.C. 331), except that any fines shall be calculated in accordance with the Criminal Fine Improvement Act of 1987, and no showing of interstate commerce shall be required.

"(c) Construction.—Nothing in this section shall be construed to preclude any person injured by a violation of this title from seeking redress in an appropriate court to remedy such violation.

"SEC. 1543. REGULATIONS.

"The Secretary shall have the authority to promulgate regulations to carry out this subtitle.

"CHAPTER 2—ADDITIVES; MISBRANDED AND ADULTERATED TOBACCO PRODUCTS

"SEC. 1551. TOBACCO ADDITIVES.

"(a) Reporting.—

"(1) In general.—It shall be unlawful for any person to manufacture, import, or package, any tobacco product brand name unless such person has provided to the Secretary, within the time periods described in paragraph (2), a complete list of—

"(A) each tobacco additive used in the manufacture of each tobacco product brand name that such person manufactures, imports, or packages; and

"(B) for each such additive, the range of the quantities of such additive used by such person in all tobacco product brand names manufactured, imported, or packaged by such person.

"(2) Time period for reporting requirement.—

"(A) Actions on date of enactment.—With respect to any tobacco product brand name manufactured, imported, or packed on the date of enactment of this title, the person manufacturing, importing, or packaging such product brand name shall provide to the Secretary the list required by paragraph (1) not later than 3 months after the date of enactment of this title.

"(B) Actions after date of enactment.—With respect to any tobacco product brand name manufactured, imported, or packed after the date of enactment of this section, the person manufacturing, importing, or packaging such product brand name shall provide to the Secretary the list required by paragraph (1) at least 3 months prior to the date on which such person commences to manufacture, import, or package such product brand name.

"(b) Analysis.—Any manufacturer, importer, or purchaser of a tobacco product shall provide the Secretary, on the request of the Secretary, with information regarding the impact of such additives on health.

"(c) Public Disclosure Requirements.—

"(1) Prescription.—Not later than January 1, 1991, the Secretary shall by regulation prescribe requirements for manufacturers to place information on packages of tobacco products or in package inserts that are provided with such products so that the public will be adequately informed of the tobacco additives contained in any brand or variety of tobacco products, except that spices, flavorings, fragrances, and colorings may be designated as spices, flavorings, fragrances, and colorings without specifically naming each.

"(2) Reductions and prohibitions on use of additives.—

"(A) Determination.—If the Secretary determines that any tobacco additive in a tobacco product, either by itself or in conjunction with any other additive, significantly increases the risk of the product to human health, the Secretary may require that such levels of the tobacco additive in the tobacco product be reduced or that it be prohibited from use.

"(B) Basis.—

"(i) In general.—The determination under subparagraph (A) shall be made by regulation.

"(ii) Comment.—Prior to the issuance of a regulation under clause (i), the Secretary shall provide notice and an opportunity for comment pursuant to section 553 of title 5, United States Code, except that the time for such comment shall not be less than 60 days. The Secretary, in the event that it appears that material facts may be in dispute concerning the proposed regulation, shall provide such appropriate opportunities for the presentation of evidence and for cross-examination of witnesses as the circumstances require either before the Secretary or an officer or employee of the Department designated by the Secretary.

"(d) Judicial Review.—Judicial review of a determination under this section shall be governed by and shall be in accordance with section 409(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(g)), except that the requirements of paragraph (3) of such subsection shall not apply.

"SEC. 1552. MISBRANDED TOBACCO PRODUCTS.

"A tobacco product shall be considered to be misbranded if it is not labeled in accordance with the requirements prescribed by the Secretary under section 1551(c)(1).

"SEC. 1553. ADULTERATED TOBACCO PRODUCTS.

"A tobacco product shall be considered to be adulterated—

"(1) if the level of any tobacco additive contained in the product is in violation of a requirement under section 1551(c)(2)(A);

"(2) if it contains any tobacco additive that has been prohibited from use under section 1551(c)(2)(A);

"(3) if it contains in whole or in part any filthy, putrid, or decomposed substance; or

"(4) if it has been prepared, packed, or held under unsanitary conditions where it may have become contaminated with filth or where it may have been rendered more injurious to health.

"SEC. 1554. EXAMINATIONS AND INVESTIGATIONS.

"(a) AUTHORITY.—

"(1) IN GENERAL.—The Office of Regulatory Affairs is authorized to conduct examinations and investigations for the purposes of this subtitle through officers and employees of the Department or through any health officer or employee of any State, territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

"(2) PUERTO RICO AND THE TERRITORIES.—In the case of tobacco products packed in the Commonwealth of Puerto Rico or a territory the Office of Regulatory Affairs shall attempt to make inspection of such products at the first point of entry within the United States, when in the opinion of the Office of Regulatory Affairs and with due regard to the enforcement of all the provisions of this title, the facilities at the disposal of the Office of Regulatory Affairs will permit of such inspection.

"(3) DEFINITION.—As used in this subsection the term 'United States' means the States and the District of Columbia.

"(b) SAMPLES.—Where a sample of a tobacco product is collected for analysis under this subtitle the Center shall, on request, provide a part of such official sample for examination or analysis by any person named on the label of the product, or the owner thereof, or the attorney or agent of such persons, except that the Secretary may, by regulation, make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as the Secretary finds necessary for the proper administration of the provisions of this subtitle.

"(c) INSPECTION OF RECORDS.—For purposes of enforcement of this subtitle, records of any department or independent establishment in the executive branch of the Federal government shall be open to inspection by any official of the Department of Health and Human Services duly authorized by the Office of Regulatory Affairs to make such inspection.

"SEC. 1555. NONTOBACCO NICOTINE CONTAINING PRODUCTS.

"Any product that contains nicotine but that is not a tobacco product as defined in section 1561, shall be considered to be a drug under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)(C)).

"Subtitle D—Miscellaneous Provisions

"SEC. 1561. DEFINITIONS.

"As used in this title:

"(1) Center.—The term 'Center' means the Center for Tobacco Products established under section 1501.

"(2) Interstate commerce.—The term 'interstate commerce' has the same meaning given such term in section 201(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(b)).

"(3) Minor.—The term 'minor' means any individual who is under the age of 18 years.

"(4) Person.—The term 'person' includes individual, partnership, corporation, and association.

"(5) Recipient.—The term 'recipient' means any entity or individual that has received a grant, contract, or cooperative agreement under this title.

"(6) Smokeless tobacco.—The term 'smokeless tobacco' means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity.

"(7) State.—The term 'State' means any State or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

"(8) Territory.—The term 'territory' has the same meaning given such term in section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)).

"(9) Tobacco additive.—The term 'tobacco additive' means any ingredient that is added to a tobacco product in the process of manufacturing or producing a tobacco product.

"(10) Tobacco product.—The term 'tobacco product' means cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, and snuff, and any other product that contains tobacco and is intended for human use.

"(11) Tobacco use.—The term 'tobacco use' means the use of any tobacco product that is used through smoking, inhalation, or mastication, and such term shall include the use of nasal and oral snuff.".

SEC. 4. DRUG-FREE SCHOOLS AND COMMUNITIES ACT OF 1986.

(a) State Programs.—Section 5122(a)(1) of the Drug-Free Schools and Communities Act of 1986 (20 U.S.C. 3192(a)(1)) is amended by inserting "and tobacco use" after "alcohol abuse".

(b) Local Drug Abuse Education Prevention Programs.—Section 5125(a) of such Act (20 U.S.C. 3195(a)) is amended—

(1) in the matter preceding paragraph (1), by inserting "and tobacco use" after "alcohol abuse";

(2) in paragraph (11), by striking out "abuse," and inserting in lieu thereof "abuse and tobacco use,";

(3) in paragraph (13), by inserting "and tobacco use" after "alcohol abuse" each place that such occurs; and

(4) in paragraph (14), by inserting "and tobacco use" after "alcohol abuse".

(c) Local Applications.—Section 5126(a)(2) of such Act (20 U.S.C. 3196(a)(2)) is amended—

(1) in subparagraph (D), by striking out "drug" and inserting in lieu thereof "drug, tobacco";

(2) in subparagraph (E), by—

(A) by striking out "applicant's drug" and inserting in lieu thereof "applicant's drug, tobacco";

(B) by striking out "and" at the end of clause (i);

(C) by inserting "and" at the end of clause (ii); and

(D) by adding at the end thereof the following new clause:

"(iii) how it will discourage use of tobacco products by students;"; and

(3) in subparagraph (I), by striking out "conduct drug and alcohol abuse" and inserting in lieu thereof "conduct drug and alcohol abuse and tobacco use".

(d) FEDERAL ACTIVITIES.—Section 5132(b) of such Act (20 U.S.C. 3212(b)) is amended—

(1) in paragraph (1), by inserting before the semicolon the following: "and for dissemination under section 1527 of the Public Health Service Act"; and

(2) in paragraph (2), by striking out "drug" and inserting in lieu thereof "drug and tobacco".

(e) DEFINITIONS.—Section 5141(b)(1) of such Act (20 U.S.C. 3221(b)(1)) is amended by striking out "alcohol" and inserting in lieu thereof "alcohol, the use of tobacco,".

SEC. 5. NATIONAL COMMISSION ON DRUG-FREE SCHOOLS.

Section 5051(i) of the Anti Drug Abuse Act of 1988 (20 U.S.C. 3172 note) is amended—

(1) in paragraph (1)—

(A) by inserting ", including anti-tobacco education," after "program" in subparagraph (A);

(B) by inserting "or tobacco products" after "drugs" in subparagraph (C); and

(C) by inserting "and tobacco" after "drug" in subparagraph (D); and

(2) in paragraph (3), by inserting "and smoke-free" after "drug-free".

SEC. 6. INCENTIVE GRANTS TO ESTABLISH SMOKE FREE SCHOOLS.

(a) IN GENERAL.—There are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993, to enable the Secretary of Education to make incentive grants to States in accordance with this section.

(b) STATE POLICY.—To receive a grant under this section, a State shall establish a policy that—

(1) creates smoke-free elementary and secondary school buildings and grounds and school buses;

(2) requires schools to establish smoking areas in which adults only are permitted to smoke, and to ensure adequate safeguards exist to protect students from exposure to smoke; and

(3) provides technical assistance to schools and other assistance to implement the provision of this section.

(c) Use of Funds.—A State receiving a grant under subsection (a) shall use such grant to disseminate materials to school personnel and students, and hold conferences and meetings, concerning the health hazards of tobacco use by students.

(d) Regulations.—The Secretary of Education, in consultation with the Secretary of Health and Human Services, shall promulgate regulations necessary to implement this section.

(e) Additional Restrictions.—A State receiving a grant under subsection (a) may place restrictions on the use of tobacco products in schools in addition to the requirements referred to in subsection (b). A State receiving funds under this section shall provide assistance under this section only to schools that are subject to the State laws described in subsection (b).

(f) Application.—No grant may be made under this section unless an application therefor is submitted to the Secretary of Education in such form, in such manner, and containing such information as the Secretary of Education shall require.

SEC. 7. TECHNICAL AMENDMENTS.

(a) Comprehensive Smoking Education Act.—Section 3 of the Comprehensive Smoking Education Act (15 U.S.C. 1341) is repealed.

(b) Comprehensive Smokeless Tobacco Health Education Act of 1986.—Sections 2, 4, 5, and 8 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401, 4403, 4404, and 4407) are repealed.

SEC. 8. STUDY AND REPORT.

(a) Requirement.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Agriculture, shall conduct the study described in subsection (b), and prepare and submit, to the appropriate Committees of Congress, a report concerning the results of such study.

(b) Content of Study.—The study referred to in subsection (a) shall—

(1) investigate the use of pesticides on tobacco and the presence of pesticides in tobacco products;

(2) analyze the effect that the presence of pesticides in tobacco products has on human health; and

(3) determine whether tolerances should be established for the use of pesticides in tobacco products.

SEC. 9. CONSTRUCTION.

Nothing in this Act, or an amendment made by this Act, shall be construed to limit, restrict, expand, or otherwise affect the authority of the Federal Trade Commission.

IV. Committee Views

SUBTITLE A—CENTER FOR TOBACCO PRODUCTS

This bill directs the Secretary of the Department of Health and Human Services to establish a new Center for Tobacco Products and appoint a Director. The functions of the Center include education about the health effects of tobacco use, research regarding patterns of use and cessation, assistance to the states to achieve further reductions of tobacco use, coordination of federal education and research activities on tobacco products, and the regulation and public disclosure of additives to tobacco products. The Center will administer several new programs through which it will expand federal efforts to educate the public about the health effects of tobacco use and reduce rates of smoking and use of smokeless tobacco.

It is the Committee's intent that the new Center be created out of the existing Office on Smoking and Health. The Committee views the Office of Smoking and Health as the obvious choice as the base of expansion of federal activities to reduce tobacco use, given the history, expertise, and contacts of that Office. The Committee has authorized $25 milliion for the activities of the Center. The budget of the Office of Smoking and Health should rise from the current level of $3.5 million to $25 million in the first year to support the expansion of operations.

SUBTITLE B—ANTI-SMOKING PROGRAMS

Chapter 1—Public information campaigns

The new programs administered by the Center will include a national information program of public service announcements and paid advertisements about the health effects of tobacco use and tobacco smoke. The Committee envisions this public information campaign as carried by diverse media, including print media, outdoor and transit advertisements, and radio and television. An authorization of $50 million is allotted to provide sufficient funding for this national effort.

The program should be designed to prevent initiation and encourage cessation of tobacco use. It should be aimed at those groups which have the greatest prevalence of tobacco use or suffer the greatest risk from tobacco use. This includes youth, school dropouts, pregnant women, minorities, blue collar workers, and low income individuals.

The Committee has particular interest in reaching youth with the public information campaign. The age of initiation of tobacco use has dropped since the first Surgeon General's report over 25 years ago. Currently, 90% of smokers begin smoking before they become twenty-one. Among high school seniors, over 50% begin by age 14 and 25% by age 12. Because nicotine is addictive, most young smokers are addicted before they understand the consequences of their actions and before they are legally old enough to smoke. Subsequently, it is difficult for them to quit. Of those high school seniors who smoke a half a pack a day, 53% try to quit but cannot. In fact, 95% of high school seniors think they will quit smoking within five years. The reality is that only 25% quit by eight years later. Education aimed at young teens and pre-teens is essential in order to provide this group with resistance skills to be used against industry promotions or peer pressures that may encourage them to smoke or use smokeless tobacco.

The Committee believes that the public information campaigns that comprise the national information program should be designed in part to specifically counter the messages contained in tobacco product advertising and promotion. Existing advertisements visually equate tobacco use with youth, action, sports, beauty, success, and popularity. These advertisements create images young people emulate and contribute to an atmosphere which encourages young people to start smoking. The Committee believes it is necessary and important to demonstrate through counter-advertising techniques that tobacco use is not equated for very long with youth, health, and vigorous activity, but rather with illness, disability, and death.

The Committee is aware of the paid advertising messages that are part of the eduational efforts of states like Minnesota and California, and of voluntary organizations like Doctors Ought to Care (DOC) in Houston. Minnesota has demonstrated the importance of paid advertising to a well rounded and effective public education campaign. The Commissioner of Health of Minnesota testified at the Committee's first hearing on February 20, 1990, that the state has leveraged additional public service announcement time from the media through its purchase of paid advertising time. The education campaign in Minnesota is credited with helping to reduce the rate of smoking to one of the lowest in the nation.

The Committee recommends attention to the counterads designed by DOC. The Committee believes there is a role for parody and humor in pointing out the misleading nature of existing tobacco advertising.

The Committee believes that counter-advertisements can both inform and discourage tobacco use among children. The counter advertising campaign carried out on national television pursuant to the Federal Communications Commission's Fairness Doctrine ruling produced a significant decrease in tobacco use.

A question has been raised about the fairness of running paid television ads about the health effects of tobacco use when no tobacco product advertising is permitted on television. The Committee notes that there is currently considerable air time devoted to the coverage of tobacco industry sponsored events. This coverage includes ubiquitous images of cigarette and smokeless tobacco brand names. A video tape which was displayed at the February 20th hearing showed many examples of tobacco product promotion on television. The Committee concludes that tobacco products are currently being promoted on electronic broadcast media. The video evidence presented at the hearing included examples of young teenagers participating in the promotional activities being broadcast. The Committee views this as inappropriate and a violation of the tobacco industry's own voluntary code on advertising practices.

The Committee believes it is essential that there be no loss of time currently devoted to public service announcements by any media because of the availability of funds to pay for ads on the same subject. The Center must obtain a written assurance from all media with which paid messages are placed that there will be no decrease in public service announcement time devoted to the reduce tobacco use. The Committee would prefer to see an airing of public service announcements at a time when they are likely to achieve a greater reach. The Committee suggests that networks which improve the placement of public service announcements to increase the reach and frequency should be considered most favorably for placement of paid advertisements.

Chapter 2—Model state leadership incentive grants for antitobacco use intervention

The Center will award 10–20 states with model state leadership incentive grants to support activities which prevent the initiation of tobacco use, promote cessation of tobacco use, or which implement and enforce existing state laws on sale of tobacco products to minors. To be designated a model state, a state must have in effect a law that prohibits the sale of tobacco products to individuals who are under the age of 18 and must seek to improve the enforcement of the law. It must also have in effect a law or regulation that is intended to reduce the use of, or access to, cigarette vending machines by minors who are under the age of 18 and must seek to improve the enforcement of that law or regulation.

In recent years, many state health directors have sought new policies and programs or strengthened policies and programs to reduce tobacco use. This expanded effort is based on national priorities as defined by the Secretary of the Department of Health and Human Services. DHHS has identified tobacco use as the number one preventable cause of death in the nation. The Department has also made a smoke-free society by the year 2000 one of its key health objectives.

State health directors have taken a fresh look at the problem in their efforts to pursue this major national public health objective. The Surgeon General has concluded that nicotine is addictive and that most smokers initiate cigarette use while they are still in their teens. At least half of all smokers initiate cigarette use while they are very young teens. Public health officials agree that in order to achieve further significant decrease in smoking prevalence, preventing the initiation of smoking by youth must occur before they become addicted.

Education is one important route to preventing the initiation of tobacco use. Another is the enforcement of state laws on sale of tobacco products to minors. In recent years, there has been renewed interest in these laws by state public health officials.

A recent report of the Office of the Inspector General (OIG) of HHS concluded that despite the fact that 44 states and the District of Columbia have laws which prohibit the sale of cigarettes to minors, children and young teens can and do buy cigarettes easily whenever they want. The OIG found that only five states could even report how many violations of their laws had been identified. These states found only 32 violations in 1989. Two thirds of the public health officials contacted by the OIG confirmed the lack of enforcement of their state's laws. Meanwhile, it is known that an estimated one billion packs of cigarettes are sold to youngsters (under the age of 18) each year.

State health directors have started to look at state laws with renewed interest. Retail establishments in virtually all states make a practice of requesting identification before they sell alcoholic beverages to an individual who could be under the legal drinking age. This simple procedure—a request for identification before the purchase of tobacco products—should be used as commonly as it is for the purchase of alcohol. The procedure is already familiar to store clerks and cashiers.

A number of state health directors are seeking ways to improve the compliance of retail establishments with state laws on sale of tobacco products. Currently, retail establishments have little knowledge of state laws. There have been few efforts to educate their owners or encourage their compliance. The public is poorly informed about the laws. Systems for enforcement are lacking.

The model state incentive program is intended to assist states in implementing, enforcing or improving these state laws. The Committee is aware of voluntary efforts already underway on the part of national and local associations of retailers to educate their membership on this issue. The committee notes that the smokeless tobacco industry has also conducted a voluntary education program emphasizing that the use of their product is strictly for adults. Their three point program involves industry support of state legislation to establish 18 years of age as the minimum age of purchase of all tobacco products; a retail education program which supports the enforcement of 18 as the mandated age of purchase, and a print program to promote its adults only message. The Commission is supportive of these efforts but believes they will have to expand considerably if they are to have any significant effect. In addition, testimony received from a police official from Woodridge, Illinois convinced the Committee that voluntary measures, even when combined with the passage of better laws, will not be sufficient to achieve compliance. Effective enforcement is essential.

In the town of Woodridge, it was shown on follow-up studies that, despite an improved law which required licensing of all tobacco venders and threatened revocation of licenses for non compliance—and an educational campaign to notify retail establishments regarding their new responsibilities—compliance remained poor until surprise enforcement campaigns were carried out and publicized.

The model state grant program will assist states to educate retailers and the public about the existence of state laws, to establish procedures for the reporting of violations, to establish routines for enforcement, and to improve access to the system of enforcement for the public. Evaluation of these efforts is an integral part of any program supported by the incentive grant. The Center should be kept abreast of state progress in developing and evaluating these systems.

Vending machine sales should also be addressed as part of state efforts to curtail tobacco sales to minors. Though vending machine sales account for about 15 percent of sales to minors, no system will be effective in eliminating sales to minors unless vending machine sales are addressed. Some states have restricted vending machine sales of cigarettes only to those locations which are off limits to minors, such as bars and liquor stores. Electronic locking devices are also in use in some areas. These may be deactivated from the cash register after verification of age has been presented to the cashier. Recently, the Secretary of Health and Human Services advocated that states ban entirely the use of vending machines which dispense cigarettes.

Chapter 3—Education to decrease tobacco use in the workplace

Worksites provide an ideal opportunity for implementing tobacco use education programs since they represent a setting in which a large number of smokers may be reached. This legislation authorizes $5 million to be spent on education programs at the workplace. Effort should be focused on preventing initiation and encouraging cessation of tobacco use.

Efforts to help motivate people to quit smoking or chewing tobacco should be directed toward those populations with the highest prevalence of tobacco use and activities should be conducted in those settings where programs are most likely to reach the intended audiences. Effort should also be directed toward populations which may be at higher risk because of combined exposure to tobacco smoke and to workplace hazards associated with respiratory disease. The Committee finds that certain groups of employees have higher smoking rates than the general population and believes that special efforts must be made to reduce tobacco use among these individuals. In 1985, the smoking prevalence rate among blue-collar workers aged 20 years and older was 39.7%, while the rate for white-collar workers was 27.5%. This difference reflects differences in educational level. In general, the rate of smoking of those with the most education is half the rate of smoking of those with the least education. Some worksites which often have high smoking rates include factories, construction sites and other places employing service personnel.

An important criterion in determining who receives these grants should be a potential for future replicability. These programs will be demonstration projects which will serve as models for other worksites to use in educating their employees and their dependents on the benefits of not using tobacco. There is a requirement that all workplace education grants would be implemented with the full cooperation of the employer. They could also be initiated by the employer.

There is growing interest on the part of employers in reducing smoking rates among their employees. This is based, in part, on economic concerns. According to the Department of Health and Human Services, some of the economic costs of smoking to employers are: $24 billion in lost productivity annually by American business due to smoking; $28 billion annually spent on medical costs—almost half of which is paid by businesses; and there are 80 million workdays lost each year to smoking-related illnesses. In addition, smoking employees are 50% more likely to be hospitalized than nonsmokers; absentee rates are 50% higher for smokers than nonsmokers.

The Committee believes that workplace efforts to reduce tobacco use among people with high usage rates should include motivation and support for smoking cessation by workers and their family members and education on the health effects of tobacco use to prevent initiation of tobacco use among employees and their families, particularly children.

The Committee views these workplace education programs as voluntary programs. The workplace education grants should not be awarded where there are policies which make the job itself, wages or other conditions of employment contingent on participation in tobacco use education or cessation programs.

Worksite wellness programs, including education and health promotion activities, have proven to be quite effective in reducing tobacco use for many employers. The Committee believes that these worksite programs will be most effective if they are developed with cooperation between employer and employee. The Committee views the following as likely recipients for the workplace education grants: state and local health departments, employee organizations (including trade unions), employers, voluntary health organizations such as the American Lung Association, the American Heart Association and the American Cancer Society, and community organizations. These organizations could develop and implement worksite smoking education programs with the agreement and endorsement of the employer.

SUBTITLE C—PROHIBITED ACTS

Chapter 1—Prohibited acts and enforcement

This chapter specifies the acts which are prohibited and the range of enforcement procedures available.

It will be unlawful for a manufacturer, to introduce or deliver for introduction into interstate commerce or to receive in interstate commerce a tobacco product that is adulterated or misbranded in violation of the requirements set forth in sections 1551–1553, and other provisions of the Act.

The Committee recognizes that the need to disclose additives to the public must be balanced with the need to protect the trade secrets of tobacco manufacturers. The Committee firmly believes that health and safety. It will be unlawful to disclose trade secret information to any person except to the Secretary of Health and Human Services and designated employees of such agency, or to the courts when such information is relevant in a judicial proceeding brought under this title. Nothing in this section shall authorize the withholding of information by the Secretary or by any officers or employees under his control from the duly authorized Committee of Congress. Any request by Congress must be accompanied by safeguards to assure the confidentiality of such information.

The Committee wants to ensure that all information that is included on or with any tobacco product is also available to the public. Such information must be made available upon written request. It should not be necessary to purchase a tobacco product in order to receive such information.

Enforcement

The Committee recognizes that the Food and Drug Administration (FDA) has established an extensive structure to enforce the requirements of the Food, Drug and Cosmetic Act. The Committee intends to provide the Office of Regulatory Affairs with similar enforcement powers as granted to the FDA.

Section 1542 authorizes enforcement of the Act through such procedures as injunctions, civil and criminal penalties, seizures and warning letters as outlined in the references to the relevant sections of the Food, Drug and Cosmetic Act. The Committee understands that the Secretary of Health and Human Services has provided guidance to the Food and Drug Administration concerning the implementation of its enforcement authority. The Committee expects that the Secretary will provide similar guidance to the Office of Regulatory Affairs as necessary.

Chapter 2—Additives; misbranded and adulterated tobacco products

The Committee recognizes that the need to disclose additives to the public must be balanced with the need to protect the trade secrets of tobacco manufacturers. The Committee firmly believes that the public is entitled to have information that may affect their health and safety. In order to achieve this balance, disclosure of additives to the public and to the Secretary is required in a manner that does not disclose specific quantities of additives to specific brands. Rather disclosure of a range of quantities for each company is required.

This legislation will make it illegal from any company to manufacture or import any tobacco brand names unless there is provided to the Secretary a complete list of each tobacco additive, including fragrances, flavorings, and colorings, used in the manufacture of each tobacco product brand name and the range of quantities of each additive used in all tobacco brand names manufactured by that company. The lists must be provided to the Secretary no later than three months after the date of enactment of the bill, or three months prior to introduction of any new brand. The manufacturer is required to provide the Secretary, on request of the Secretary, with information regarding the impact of any additive on health.

Under the terms of this provision, manufacturers would be required to disclose to the public on tobacco product packages or in package inserts, the additives contained in such product, except that flavorings, fragrances, and colorings may be designated as such without specifically naming each. Disclosure on the product carton is not sufficient.

If the Secretary determines that any additive, either by itself, or in conjunction with any other addivitive, significantly increases the risk of the product to human health, the Secretary may require that such use of the tobacco additive be reduced or prohibited.

The authority for additive regulation will reside in an Office of Regulatory Affairs within the Public Health Service established or designated from among existing entities by the Secretary.

In 1984, with the passage of the Comprehensive Smoking Education Act, P.L. 98-474, a requirement was established that cigarette manufacturers report additives to the Secretary of Health and Human Services. The Secretary was directed to report to the Congress on "any such ingredient which in the judgment of the Secretary poses a health risk to cigarette smokers." The legislated reporting system requires that the company using a particular additive and the brand in which a particular additive was contained no be revealed. There is no requirement for the industry to report quantities of any additive used or even the range of any particular additive used by any company. As a result, annual reports which have gone to the Secretary have been composite lists of cigarette additives used by cigarette producing companies. With no information about quantity, brand, or company, the composite lists which have been compiled and presented annually to the Secretary have provided no useful information from which the Secretary can make a judgment on the health risk to cigarette smokers posed by such additives.

The Committee believes that it was the intent of Congress in 1984, when P.L. 98-474 was signed into law, to provide the Secretary with useful information for which to make the kind of judgment it requested. Clearly that objective was not achieved by the reporting requirement which was established. The Committee believes it is time to follow through on the intent of Congress as indicated by the passage of the earlier legislation. The reporting requirement contained in this bill should result in useful information so that judgments about the risk of individual additives or combinations of additives will be technically feasible.

The Committee has the firm conviction that information about additives to tobacco products should be available to the consumer in parallel with the requirements that apply to additives to foods, drugs, or cosmetics.

The Committee believes that the requirements of this section will protect trade secrets. The Committee is aware of the considerable concern on the part of individual companies regarding protection of the formulation for their individual products. The provisions of this section have been carefully designed to permit disclosure to the public of basic information to which they are entitled regarding the component additives of the products they purchase, while protecting key information that might reveal the exact formulation of the product. Fragrances, flavorings, spices, and colorings may be designated as such; individual fragrances, flavorings, and colorings do not have to be itemized on the package. Only the range of quantities of each additive and not the specific quantity of each additive will be required to be revealed to the Secretary by each company for their products. This will allow the Secretary to develop models for different combinations of additives and make initial judgments about an approach for analysis and data collection.

The Committee recognizes that there are differences among tobacco products. Since there are dozens of cigar and pipe tobacco manufacturers, and a great multiplicity of products (there are about 4,500 different cigar shapes and sizes, for example) the ability of manufacturers in the cigar and pipe tobacco industries to comply with the legislation will be hampered. Some information must be obtained from suppliers who may regard the information as proprietary, thus there may have to be negotiations between the manufacturers and their suppliers. Given the Committees interest in disclosure of non-tobacco additives, the Committee nevertheless feels that the tobacco products should be subject to the reporting requirements contained in the Act. The Committee recognizes that manufacturers of cigars and pipe tobacco may need additional time to comply with the reporting and disclosure requirements imposed by the Act.

It has been suggested to this Committee that a model for the regulation of additives to tobacco products may be found in the system of regulation of food additives. The GRAS list (Generally Recognized as Safe) has been suggested as a starting point for separating tobacco additives into those which need analysis and those which do not. While this system may hold some promise as an approach to the regulation of additives to smokeless tobacco, the GRAS list may have little relevance to cigarette additives which are ingested in a different manner.

SUBTITLE E—MISCELLANEOUS PROVISIONS

Tobacco in the Drug-Free Schools Act

The Surgeon General's 1988 report on "The Health Consequences of Smoking: Nicotine Addiction" demonstrates "conclusively that cigarettes and other forms of tobacco are addicting in the same sense as are drugs such as heroin and cocaine." Because the addictive nature of nicotine makes it very difficult to stop smoking, the Committee believes that preventing adolescents from ever beginning to smoke is essential.

Tobacco use is generally not perceived to be as serious in nature as is the use of illicit drugs. Nor is tobacco associated with the social disruption, crime and violence which are often related to the use of illicit drugs. However, the health implications of tobacco use remain far more severe. Nearly 400,000 people die each year in the United States from tobacco-related diseases. This number is far greater than the number of deaths from alcohol and drug use and all related fatalities combined. Given the magnitude of the problem and the addictive nature of nicotine in tobacco products, the Committee believes it is imperative that information on the health effects of tobacco use be included in the education programs of the Drug Free Schools and Communities Act of 1986. Consistent with the Committee's view the curricula which have resulted from that program do already include information about the problem of tobacco use, as one of the basic educational tenents. In that regard, the Committee supports the current curricula.

The Committee believes that schools are one of the most appropriate arenas for conveying information since they provide access to nearly all children at an age young enough to have significant potential for preventing the onset of tobacco use. To be most effective in preventing children from using tobacco products, it is important to reach them while they are young—50% of all smokers begin by age 14.

The Committee believes that all children should be free from the influence of and exposure to tobacco, particularly while in school. The National Commission on Drug-Free Schools is preparing recommendations on school policies that will encourage the establishments of drug free schools. This legislation would elicit recommendations on policies that also encourage the establishment and maintenance of smoke-free schools.

Recent studies by the U.S. Environmental Protection Agency indicate that 3,800 people die in the U.S. each year from lung cancer caused by exposure to environmental tobacco smoke. Other recent evidence concludes that passive smoke causes 32,000 heart disease deaths each year in this country. For every 8 deaths attributed to smoking, there is one additional death attributed to passive smoking. The Committee believes that policies against smoking on school grounds or at school-sponsored events should be established and enforced. Clean indoor air is an important component of protecting everyone's health, particularly those young children whose respiratory systems are still developing.

The Committee believes that equally important as the absence of involuntary smoke to the development and health of children, is the presence of visible, nonsmoking role models for all those impressionable children who will be making a decision about whether to smoke during the school years. A school environment where teachers, parents, coaches and peers do not smoke can have a critical influence over these young people by providing a consistent and inescapable message that smoking is unhealthy behavior.

The Committee believes that (schools) should play an active role in effective tobacco education. To encourage States to establish smokefree school environments, this bill will provide incentive grants to those States which establish policies creating smokefree elementary and secondary schools. These grant funds may be used to educate faculty, administrators, parents and students about the health effects of environmental tobacco smoke, the addictive nature of nicotine, and the importance of preventing all forms of tobacco use. Specific activities may include speakers, media events, development and dissemination of materials, appropriate social events, and other activities.

V. History of the Legislation

The Tobacco Product Education and Health Protection Act, a bill to amend the Public Health Service (PHS) Act to establish a Center for Tobacco Products, to inform the public concerning the hazards of tobacco use, to disclose and restrict additives to such products, and to require labeling of such products to provide information concerning such products to the public, and for other purposes, was introduced by Senator Kennedy on November 15, 1989, and was referred to the Senate Committee on Labor and Human Resources. The Committee held hearings on the bill on February 20 and April 3, 1990. The following persons appeared as witnesses at the February 20 hearing: Senator Frank R. Lautenberg; Senator Bill Bradley; and Representative Richard J. Durbin; Dr. Louis W. Sullivan, Secretary, Department of Health and Human Services; Dr. Alan Blum, Baylor College of Medicine; Charles O. Whitley, The Tobacco Institute; Thomas Hale Boggs, Jr., the Freedom to Advertise Coalition; Scott D. Ballin, the Coalition on Smoking OR Health; Sister Mary Madonna Ashton, Minnesota Commissioner of Health.

The following witnesses appeared at the April 3 hearing: Representative Thomas A. Luken; Representative Stephen L. Neal; Officer Bruce R. Talbot, the Woodridge, Illinois, Police DARE (Drug Abuse Resistance Education) Program; John J. Joyce, the Maine Grocers Association; Peter Strauss, the National Association of Tobacco Distributors; Dr. Gary Williams, the American Health Foundation; John Rupp, Covington & Burling; Burt Neuborne, the Freedom to Advertise Coalition; Vincent A. Blasi, Columbia University School of Law; Morton H. Halperin, the American Civil Liberties Union; Floyd Abrams, The Tobacco Institute.

The Committee met on May 16, 1990, and ordered the bill reported, with amendments.

VI. COMMITTEE ACTION AND VOTES IN COMMITTEE

The Tobacco Product Education and Health Protection Act of 1990 was brought before an Executive Session of the Labor and Human Resources Committee for mark-up as an Original Bill on May 16, 1990. There were no amendments offered. The measure was approved by a vote of 10 to 4.

VII. COST ESTIMATES

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 19, 1990.

Hon. EDWARD M. KENNEDY,
Chairman, Labor and Human Resources,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for the Tobacco Product Education on Health Protection Act of 1990, as ordered reported by the Senate Committee on Labor and Human Resources on May 16, 1990.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

ROBERT F. HALE
(For Robert D. Reischauer).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: None.
2. Bill title: Tobacco Product Education and Health Protection Act of 1990.
3. Bill status: As ordered reported by the Senate Committee on Labor and Human Resources on May 16, 1990.
4. Bill purpose: To amend the Public Health Service Act to establish a center for tobacco products, to inform the public concerning the hazards of tobacco use, to provide for disclosure of additives to such products, and to require that information be provided concerning such products to the public, and for other purposes.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Estimated authorization levels:					
Center for Tobacco Products	25	26	27		
Information campaign grants	50	52	54		
Model State grants	25	26	27		
Workplace tobacco use grants	5	5	5		
Smoke free schools grants	5	5	5		
Office of Regulatory Affairs	7	7	8	8	8
Reports	1		(1)		(1)
Total estimated authorization levels	118	122	126	8	8
Estimated outlays:					
Center for Tobacco Products	13	21	25	12	5

[By fiscal years, in millions of dollars]

	1991	1992	1993	1994	1995
Information campaign grants	27	41	50	25	11
Model State grants	13	21	25	12	5
Workplace tobacco use grants	3	4	5	2	1
Smoke free schools grants	1	4	5	5	1
Office of Regulatory Affairs	6	7	8	8	8
Reports	([1])	([1])	([1])	([1])	([1])
Total estimated outlays	63	97	118	65	31

[1] Details in this table may not add to totals because of rounding

The costs of this bill fall within budget functions 500 and 550.

Basis of estimate: This bill would establish a center for tobacco products, and create a number of grant programs to educate the public on the hazards of tobacco products in order to discourage the initiation of, and encourage the cessation of, tobacco use.

The bill specifies the authorization levels for the grant program to reduce tobacco use in the workplace. The bill also provides specific authorization years 1992 and 1993 for the center for tobacco products, the information campaign grant program, model state grant program, and the smoke free school grant program. The CBO estimated the 1992 and 1993 authorization levels for these activities by increasing the respective 1991 authorization by projected inflation.

The bill would require the Secretary of Health and Human Services (HHS) to establish, or to designate an existing entity as, the Office of Regulatory Affairs, which would insure against misbranded or adulterated tobacco products through examinations and investigations. The bill does not specify an authorization level for this activity. Based on the costs of the Department of Agricultukre's imported tobacco inspection program, CBO estimates that it would cost approximately $7 million to establish and maintain an office that inspected tobacco products within the United States.

The bill would require the Secretary of HHS to submit an initial report to Congress in 1991, and a biennial report thereafter, that describes the effects of health education efforts on the use of smokeless tobacco and evaluates the health effects of using smokeless tobacco products. CBO estimates that this report would cost less than $500,000 in fiscal years 1991, 1993, and 1995. Also, within one year of enactment of the legislation, the Secretary would have to report on the use of pesticides on tobacco and the effect of those pesticides on human health. CBO estimates that the study and report would cost less than $500,000 in fiscal year 1991.

This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year, Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Estimated cost to State and local government: None.
7. Estimate comparison: None.
8. Previous CBO estimate: None.
9. Estimate prepared by: Karen Graham and Deborah Kalcevic.

10 Estimate approved by: C.G. Nuckols (for James L. Blum, Assistant Director for Budget Analysis).

VIII. TOBACCO REPORT—REGULATORY IMPACT

This legislation confers new authority on the Secretary of Health and Human Services for the regulation of additives to tobacco products. There are two parts to that authority. The first is the disclosure to the public on the package or in a package insert of the additives to tobacco products; flavorings, fragances, and colorings may be disclosed as such without being specifically itemized. The Committee anticipates that sample packages or package inserts will be submitted to the Secretary within the required period of time. New brands will submit such samples prior to brand release.

The second part of the authority is the power to require the restriction or deletion of any given additive which is judged to significantly increase the risk of the product. A set of procedures and protocols will need to be developed to collect and evaluate the data by which any such conclusion may be reached and to notify the company effected if restrictions or deletions are required.

The legal basis for the new authority is carefully patterned after that currently held by the Food and Drug Administration. As such, there should be sufficient existing expertise within the Public Health Service with which to plan and construct the organization that will be required to administer this authority. An Office of Regulatory Affairs is vested with these responsibilities. It may be created or designated from among existing entities.

IX. SECTION-BY-SECTION ANALYSIS

Section 1 of the bill provides that this Act may be cited as the "Tobacco Product Education and Health Protection Act of 1990."

Section 2(a) includes the findings of the Congress relating to the bill:

> Despite a steady decline in tobacco consumption, 52,000,000 Americans still use tobacco products annually;
>
> Tobacco use causes nearly 400,000 deaths each year in the U.S., over 1,000 deaths a day;
>
> Tobacco use is the most important cause of death and illness in the U.S., causing one-sixth of all deaths annually;
>
> In 1985, the private and public sectors in the U.S. spent approximately $22 billion on smoking-related illnesses and absorbed $43 billion in economic losses from such illnesses;
>
> 50 percent of all smokers begin using tobacco by age 14, and 90 percent of all smokers begin before age 20;
>
> Nicotine-containing tobacco products are addictive;
>
> Most young people initiate tobacco use and become addicted before they are sufficiently informed or mature enough to make an informed choice concernig their use;
>
> The tobacco industry contributes significantly to the experimentation with tobacco and the initiation of regular tobacco use by children and young adults through its advertising and promotion practices;
>
> In 1988 the tobacco industry spent $3.25 billion on the advertising and promotion of tobacco products, ranking such products amongh the most heavily advertised and promoted products in the U.S.;

The tobacco industry claims that the purpose of advertising is to influence consumer brand selection, but only 10 percent of tobacco users switch brands each year;

Convincing evidence demonstrates that tobacco advertising is predominantly directed at market expansion or retention or both;

The tobacco industry must attract 6,000 new smokers daily to replace those who stop smoking or who die of smoking-related diseases and other causes;

Tobacco product advertising and promotion are intended to capture the youth market and seek to do so through advertisements that suggest a strong association between smoking and physical fitness, attractiveness, success, adventure, and independence, and that have impact on minors, who are more vulnerable to image-based advertising;

Serious gaps in knowledge about the harmful effects of tobacco use persist in both minors and the adult population, with surveys showing that large numbers of persons are unaware that smoking causes lung cancer, heart disease, and stillbirths in pregnancy;

Education is effective in preventing and halting the use of tobacco products;

The proportion of smokers among the most educated adults is less than half that among the least educated adults;

The highest percentage of smoking is among those individuals with the least amount of education, including young citizens, blue-collar workers, high school dropouts, and minorities;

The total resources of the major voluntary organizations that sponsor educational activities on smoking have never exceeded 2 percent of tobaco industry expenditures for the promotion of tobacco;

Cooperative Federal-State efforts will encourage more effective action to limit the sale of tobacco products to mixers; and

The American public and groups with highest prevalence of tobacco use should be informed about the dangers of tobacco;

Although most States prohibit the sale of tobacco products to minors, such laws are not uniformly enforced;

In recent years, there have been efforts in some States to improve the enforcement of existing laws which prohibit the sale of tobacco products to minors;

Children and teenagers should be informed about the dangers of smoking and be discouraged from initiating the use of tobacco;

No Federal law currently requires public disclosure of the numerous additives in tobacco products.

Section 2(b) lists the following purposes of this legislation:

Help educate citizens to prevent initiation and encourage cessation of tobacco use;

Inform the public about the harmful effects of tobacco products;

Support State efforts to improve educational programs for the prevention and cessation of tobacco use;

Support State efforts to strengthen laws limiting the sale of tobacco products to minors;

Determine the risk of additives of tobacco products to individual health and establish Federal regulatory authority over such additives;

Ensure the disclosure of accurate information to the public.

Section 3 of the bill amends the PHS Act by inserting a new title XV—Tobacco Health and Education Programs. Subtitle A of the new title XV directs the Secretary to establish the Center for Tobacco Products to be headed by a Director. The functions of the Center shall be to—

Educate the public concerning the health consequences of using tobacco products, provide outreach services to youth, and promote cessation of tobacco product use through the provision of technical and material assistance to States, workplaces, and the media;

Support research efforts concerning patterns of tobacco use and cessation;

Provide assistance to States to enhance their efforts to enforce existing State laws concerning the sale of tobacco products to minors within the State;

Coordinate the education and research activities of the Federal Government with regard to tobacco products;

Document the additives that are contained in tobacco products, determine the additives that represent a health risk, and ensure the disclosure of such information to the public but in a manner that assures the protection of proprietary information; and

Carry out the programs established by the Secretary under the title.

Section 1501(c) authorizes the Secretary, through the Center, to enter into contracts and agreements with agencies within and outside of the PHS to carry out this title. Section 1501(d) authorizes appropriations of $25 million for FY 1991 and such sums as may be necessary for each of FY 1992 and 1993 to carry out this section.

Section 1502 of the new title XV directs the Secretary, through the Center and in cooperation with non-Federal organizations, to carry out educational and research activities, including:

The preparation and distribution of materials to educate the public concerning the health effects of using tobacco products;

The preparation of public service announcements and the preparation and implementation of educational campaigns (including paid advertising) to inform specific propulations, including youth and the general population, of the health effects of using tobacco products and the opportunities for prevention and cessation of such use;

The provision of information to film makers, broadcast media managers, and others regarding the role of the media in promoting tobacco use behavior;

The conduct of research on patterns of tobacco product use, initiation and cessation, and effective methods for disseminating such information;

The development of plans to effectively provide outreach services to high risk groups and youth with such information; and

The conduct of reviews of the effectiveness of information required to be contained in rotating warning labels and the undertaking of research to establish how to improve the effectiveness of such labels.

Subtitle B of the title XV is entitled "Anti-Smoking Programs". Under Chapter 1—Public Information Campaigns—of this subtitle, section 1511 authorizes grants for public information campaigns. Section 1511(a) directs the Secretary to make grants to public or nonprofit private entities, or enter into contraacts or cooperative agreements with private entities, to conduct public information campaigns concerning the use of tobacco products. Subsection (b) describes the activities that will be supported under this chapter, including development of a public information campaign with public service announcements, paid educational messages for print media, public transit advertising, electronic broadcast media, and any other appropriate mode of conveying information. Such activities shall focus on discouraging youth and nonusers from using tobacco products, encourage cessation of tobacco use, and counter messages in tobacco advertisements. Activities shall focus on one or more of the specific groups described in (c).

Subsection (c) of section 1512 directs the Secretary to publish criteria for awarding grants. Criteria shall ensure that the applicant—

will conduct activities to educate one or more communities or groups with high prevalences of tobacco use and high health risks from tobacco use, specifically youth, school dropouts, pregnant women, minorities, blue collar workers, and low income individuals;

has a record of high quality campaigns of a comparable type; and

has a record of high quality campaigns that educate the population groups specified above.

Subsection (d) requires the Secretary, in awarding grants, contracts, and agreements under this chapter, to give preference to applicants that will conduct activities most likely to encompass an audience that includes several of the groups identified above. In awarding grants, contracts, or agreements, the Secretary shall attempt to distribute them so that all of the groups identified above are reached with diverse media. Single awards will not be required to reach all groups or use all media.

Section 1512 describes application requirements for public information campaign grants, contracts, or cooperative agreements. No grant, contract, or cooperative agreement shall be made or entered into unless the application meets such requirements. An application must provide such agreements, assurances, and information, and be in such form and submitted in such manner as the Secretary shall prescribe, and shall contain:

A complete description of the plan of the applicant for the development of a public information campaign, including—

An identification of the specific audiences to be educated by the campaign including one or more communities or groups with high prevalences of tobacco use and high health risks from tobacco use, such as youth, school dropouts, minorities, blue collar workers, pregnant women, and low income individuals;

An identification of the media to be used in the campaign and the geographic distribution of the campaign;

A description of plans to test market the campaign with a relevant population group and in a relevant geographic area; and

An assurance that effectiveness criteria will be implemented prior to the completion of the final plan including an evaluation component to measure the overall effectiveness of the campaign; and

A complete description of the kind, amount, distribution, and timing of informational messages and an assurance that the applicant will work with any media organizations or other groups with which such messages are placed to ensure that such organizations or groups will not lower the current frequency of public service announcements.

Section 1513 authorizes appropriations of $50 million for FY 1991 and such sums as may be necessary in each of FY 1992 and 1993 for grants, contracts, or agreements under this chapter.

Chapter 2 of Subtitle B authorizes Model State Leadership Incentive Grants for Anti-Tobacco Use Intervention. Section 1515(a) directs the Secretary, through the Center, to designate not less than 10 nor more than 20 States as model States under subsection (b) and make grants to each such State to assist in meeting the costs of improving State leadership concerning activities that—

Will prevent the initial use of tobacco products by minors;

Will encourage the cessation of the use of tobacco products among youth and other residents of the State, with particular attention directed towards those individuals and groups who are at high risk and suffer high prevalences of tobacco use, including school dropouts, minorities, low-income individuals, pregnant women, and blue collar workers; and

Will implement and enforce a prohibition on the sale of tobacco products to minors.

Subsection (b) of section 1515 provides that, to be designated a model State, a State shall—

Have in effect a law that prohibits the sale of tobacco products to individuals under age 18;

Seek to improve the enforcement of such law;

Have in effect a law or regulation intended to reduce the use of, or access to, cigarette vending machines by minors under age 18; and

Seek to improve the enforcement of such law or regulation.

Section 1516 provides that a State application for designation as a model State—

Includes a designation of a lead agency in the State that will work with the Center and contain assurances that such agency—

Has experience in matters that affect the public health;

Has expertise regarding health effects and use of tobacco products;

Provides direct services for smoking cessation or referrals for such services;

Administers activities intended to prevent the initiation of use of tobacco products by minors under age 18, and by other individuals;

Will have a lead office or division that will be chiefly responsible for such functions; and

Provide personnel sufficient to staff the lead office or division;

Provides assurances that as part of a program to improve State enforcement of existing laws on sale to minors the State will—

Establish a mechanism for the reporting of a citizen or other complaints to the responsible lead office or division concerning retail establishments that sell tobacco products to minors who are in violation of State law;

Establish a program to make the public aware of the lead office or division;

Establish a procedure by which the State may make a finding or a presumption that a retail establishment has a pattern or practice of selling tobacco products to minors in violation of State law; and

Establish a procedure for the lead State agency to report periodically to the Center regarding the system developed above;

Includes a complete description of the type of programs that will be established or assisted by or through the applicant, and a statement of goals, objectives, and timetables of such programs or activities that are consistent with the purposes of section 1515;

Specifies how the State will meet the criteria in section 1517;

Includes copies of State laws and regulations described in sections 1515(b) (1) and (3); and

Be in such form, submitted in such manner, and contain such information as the Secretary shall require, including such other information as the Secretary may by regulation prescribe.

Section 1517 directs the Secretary, acting through the Director of the Center, to establish criteria for awarding grants under this chapter, including requirements that the State must provide—

Evidence that the State has made efforts to discourage smoking and other tobacco use among the youth residing in such State;

Evidence of the need of the State for the assistance that is requested as reflected in the prevalence of the use of tobacco in the State, especially among populations described in section 1515(a)(2) above, and assurances that the State intends to concentrate its efforts on such populations;

Evidence of the need of the State for the assistance that is requested as reflected in the necessity for the development of statewide expertise in the planning of, and implementation of anti-tobacco use interventions;

Evidence of cooperative arrangements that the applicant has, or will enter into, with other entities that will participate in the activities established or assisted under the grant.

Section 1518 directs the Center to provide to designated model States, on request—

Model printed materials for distribution to retail establishments concerning the health hazards and the illegality of the sale of tobacco products to minors;

Support for and assistance in, the planning of meetings, conferences, and conventions to educate retail establishments concerning the health hazards associated with tobacco products, the addictive nature of tobacco products, and State laws that prohibit the sale of tobacco products to minors;

Technical assistance in the development of reporting systems to identify specific retail establishments and retail chains that consistently sell tobacco products to minors in violation of State law;

Assistance in the development of notification systems to make specific retail establishments aware that such establishments are acting consistently in violation of State law; and

Model notices to be distributed to retail establishments concerning the awareness of State authorities and of the Center of the continued sale of tobacco products to minors in violation of State law.

Section 1519(a) authorizes appropriations of $25 million for FY 1991 and such sums as may be necessary for each of FY 1992 and FY 1993 for grants under this chapter. Subsection (b) provides that funds under this chapter shall be distributed so that no State shall receive more than $2 million for each fiscal year under this section.

Chapter 3 of Subtitle B of title XV authorizes a program of Education to Decrease Tobacco Use in the Workplace. Section 1521 directs the Secretary, through the Center, to make grants to public and nonprofit entities and enter into contracts or cooperative agreements with private entities (including employer organizations and employer and employee consortia) for educational activities to reduce the incidence of tobacco use among workers with high prevalence of tobacco use. Such grants or contracts shall be used for meeting all or part of the cost of activities that will prevent the initiation, and encourage the cessation, of the use of tobacco products among workers and their families. Priority will be given to applicants that educate groups with high prevalence of tobacco use.

Section 1522(a) provides that assistance provided under this chapter shall be used for—

Education to promote the cessation of tobacco use among workers who have high prevalences of tobacco use;

Information and activities to provide family members of workers with education concerning the health consequences of tobacco use;

Training and education to develop the expertise of a health educator or other personnel who will perform the activities described in this subsection for workers and their families; and

The development of audio, visual, or print materials that will facilitate any of the activities described in this subsection when such appropriate materials are not otherwise available.

Section 1522(b) directs the Secretary, through the Center, to establish criteria for awarding grants under this chapter including requirements that the applicant provide to the Secretary—

Evidence of—

The potential for success of the proposed plan of the applicant; and

The existence of any cooperative arrangements with other entities that will participate in the proposed plan;

An agreement that the activity is implemented with the cooperation of the employer; and

Any other information that the Secretary specifies.

Section 1523 provides that no grant, contract, or cooperative agreement shall be made under this chapter unless an application has been submitted to, and approved by the Secretary. An application shall be submitted in such form and such manner as the Secretary shall prescribe and shall contain—

A complete description of the type of educational activities that the applicant intends to carry out with assistance provided under this chapter, including—

A description of the activities that are designed to establish an ongoing anti-tobacco program that may include working cooperatively with existing anti-tobacco programs in the community or State; and

An assurance that such activities will demonstrate a concentration of effort to change tobacco use behavior in groups identified in section 1521 and will include one or more of the activities described in section 1522;

An assurance by the applicant of its ongoing commitments to support the anti-tobacco use activities after the period of the grant, contract or cooperative agreement has expired;

A description of the manner in which the applicant will meet the critera specified in section 1522; and

Such other information as the Secretary may prescribe by regulation.

Section 1524 authorizes appropriations for grants, contracts, or agreements under this chapter of $5 million for each of FY 1991 through 1993.

Chapter 4 of subtitle B of the new title XV is entitled "Information Regarding Cigarette Smoking." Section 1526 of this chapter includes definitions for the following terms used in the chapter.

"Committee" means the committee established under section 1528(c) below, or the committee established under section 3(b) of the Comprehensive Smoking Education Act as such section existed before the date of enactment of this section.

"United States," when used in a geographical sense, includes the States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Island, and the installations of the Armed Forces.

Section 1527 directs the Secretary to establish and carry out a program to inform the public of the dangers to human health presented by cigarette smoking. Subsection (b) requires the Secretary, in carrying out this program, to—

Conduct and support research on the effects of cigarette smoking and of passive smoke on human health and develop materials for informing the public of such effects;

Coordinate all research and educational programs and other activities within the Department of HHS that relate to the effect of cigarette smoking and passive smoke on human health and coordinate, through the Committee, with similar activities of other Federal agencies and of private agencies;

Establish and maintain liaison with appropriate private entities, other Federal agencies, and State and local public agencies concerning activities relating to the effect of cigarette smoking and passive smoke on human health;

Collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking and passive smoke on human health, and develop standards, criteria, and methodologies to improve information programs related to smoking and health;

Compile and make available information on State and local laws relating to the use and consumption of cigarettes;

Establish an outreach program to inform individuals under age 18 about the health consequences of smoking; and

Undertake any other additional information and research activities that the Secretary determines necessary and appropriate to carry out this section.

Subsection (c) of section 1527 directs the Secretary to establish an Interagency Committee on Smoking and Health to carry out the coordination and liaison function described in subsection (b) above. The subsection provides for the composition of the Committee, the designation of a Chairperson, expenses for Committee members, and other information for the Committee.

Subsection (d) of section 1527 requires the Secretary, not later than January 1, 1991, and biennially thereafter, to prepare and submit, to the appropriate congressional committees, a report containing—

An overview and assessment of Federal activities undertaken to inform the public of the health consequences of smoking and passive smoke and the extent of public knowledge of such consequences;

A description of the activities of the Secretary and the Committee under subsection (a);

Information regarding the activities of the private sector taken in response to the effects of smoking on health; and

Such recommendtions as the Secretary may consider appropriate.

Section 1528 authorizes a program of public education regarding smokeless tobacco. Subsection (a) directs the Secretary to establish and carry out a program to inform the public of dangers to human health resulting from the use of smokeless tobacco products. In carrying out such program, the Secretary, through the Center, shall—

Develop educational programs and materials and public service announcements on the dangers to human health from the use of smokeless tobacco;

Make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate;

Conduct and support research on the effect of smokeless tobacco and health;

Collect, analyze, and disseminate information on smokeless tobacco and health.

Subsection (a) also requires the Secretary to consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of smokeless tobacco product manufacturers, and other appropriate entities in developing programs, materials and announcements.

Subsection (b) of section 1528 authorizes the Secretary to provide technical assistance and make grants to States—

To assist in the development of programs, materials, and announcements on the dangers to human health from smokeless tobacco use;

To assist in the distribution of such programs, materials, and announcements through the States; and

To assist States in enacting laws to establish 18 as the minimum age for the purchase of smokeless tobacco.

Section 1529 directs the Secretary, not later than January 1, 1991, and biennially thereafter, to prepare and sumbit, to the appropriate committees of Congress, a report containing—

A description of the effects of health education efforts on the use of smokeless tobacco products;

A description of the use by the public of smokeless tobacco products;

An evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research; and

Such recommendations for legislation and administrative action as the Secretary considers appropriate.

Chapter 5 of subtitle B of title XV describes General Provisions of the subtitle.

Section 1535(a) provides for the amount and method of payment of a grant, contract, or agreement awarded under this subtitle. Section 1535(b) provides for maintenance of effort under grants, contracts, or agreements awarded under this subtitle. Subsection (c) authorizes the Secretary to reduce the amount of a grant, contract, or agreement under this subtitle, at the request of a recipient, by the value of supplies or equipment furnished to the recipient by the Secretary, by the amount of pay, allowances, travel expenses, or other incurred costs of a Federal officer or employee detailed to the recipient. Subsection (d) of section 1535 requires each recipient of a grant, contract, or agreement under this subtitle to keep appropriate records as determined by the Secretary. Subsection (e) provides for the Secretary and the Comptroller General of the U.S. to have access to any books, documents, papers, and records of a recipient under this subtitle, for the purpose of conducting audits and examinations.

Subtitle C of title XV of the PHS Act as authorized by the bill is entitled "Prohibited Acts, Enforcement, and Additives". Under Chapter 1—Prohibited Acts and Enforcement—Section 1541(a) lists the following prohibited acts:

Failure of a manufacturer to comply with section 1551;

The introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded;

The adulteration or misbranding of any tobacco product in interstate commerce;

The receipt in interstate commerce of any tobacco product that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

The using by any person to that person's own advantage, or revealing, other than to the Secretary or other Department officers or employees, or to the courts when relevant in a judicial proceeding under this title, any information acquired under authority of the title concerning any method or process that as a trade secret is entitled to protection. This is not to be construed to prohibit disclosure of information to Congress;

The representation or suggestion that an approval of any tobacco product is in effect under this title or any other Federal law or regulation;

The failure of the manufacturer of a tobacco product to maintain for transmittal, or to transmit, to any individual who makes a written request for information as to such product, true and correct copies of all printed matter that are required to be included in or on any package of a tobacco product.

The failure to make reports required, the failure to retain records required, or the failure to meet requirements prescribed, under this title.

Section 1541(b) directs the Secretary, in carrying out this subtitle, to establish within the PHS, or designate an existing entity in the PHS as, an Office of Regulatory Affairs to coordinate its work with other offices and agencies of the Federal Government.

Section 1542 provides for enforcement of the provisions of this title. Subsection (a) provides that any person who violates the provisions of this title shall be subject to the penalties described in subsection (b). Subsection (b) gives the district courts of the U.S. jurisdiction to enforce violations of section 1541 in the same manner as described under specific sections of the Federal Food, Drug, and Cosmetic Act with respect to violations of section 301 of such Act, except that any fines shall be calculated in accordance with the Criminal Fine Improvement Act of 1987 and no showing of interstate commerce shall be required. Subsection (c) provides that nothing in this section shall be construed to preclude any person injured by a violation of this title from seeking redress in an appropriate court to remedy such violation.

Section 1543 authorizes the Secretary to promulgate regulations to carry out this subtitle. Chapter 2 of Subtitle C deals with Additives; Misbranded and Adulterated Tobacco Products. Section 1551(a)(1) makes it unlawful for any person to manufacture, import, or package, any tobacco product brand name unless the person has provided to the Secretary, within specified time periods, a complete list of—

Each tobacco additive used in the manufacture of each tobacco product brand name that the person manufactures, imports, or packages; and

For each additive, the range of quantities used.

Section 1551(a)(2) establishes time periods for reporting requirements. With respect to a tobacco product brand name manufactured, imported, or packed on the date of enactment, the manufacturer, importer, or packager is required to provide to the Secretary the require list not later than 3 months after the date of enactment. With respect to a product brand name manufactured, imported, or packed after the date of enactment, the manufacturer, importer, or packager is required to provide to the Secretary the required list of at least 3 months prior to the date on which the person commences to manufacture, import, or package such product brand name.

Section 1551(b) requires any manufacturer, importer, or purchaser of a tobacco product to provide the Secretary, on request, with information regarding the impact of such additives on health. Subsection (c) authorizes the following disclosure requirements—

> Not later than January 1, 1991, the Secretary is required to prescribe requirements for manufacturers to place information on tobacco product packages or in package inserts, that are provided with such products, so that the public will be adequately informed of the tobacco additives contained in any brand or variety of tobacco products except that spices, flavorings, fragrances, and colorings may be so designated without naming each.
>
> If the Secretary determines that any additive, either by itself or in conjunction with any other additive, significantly increases the risk to human health, the Secretary may require that such levels of the additive in the tobacco product be reduced or that it be prohibited from use—
>
> > Such determination shall be made by regulation;
> >
> > Prior to issuing such a regulation, the Secretary is required to provide notice and an opportunity for comment pursuant to section 553 of the title 5, U.S. Code, except that the time for such comment shall not be less than 60 days. In the event that it appears that material facts may be in dispute concerning the proposed regulation, the Secretary is required to provide appropriate opportunities for presentation of evidence and for cross-examination of witnesses as circumstances require either before the Secretary or a Department officer or employee designated by the Secretary.

Section 1551(d) provides that judicial review of a determination under this section be governed by and in accordance with section 409(g) of the Federal Food, Drug, and Cosmetic Act, except that the requirements of paragraph (3) shall not apply.

Section 1552 provides that a tobacco product shall be considered to be misbranded if it is not labeled in accordance with the requirements prescribed by the Secretary under section 1551(c)(1).

Section 1553 provides that a tobacco product shall be considered to be adulterated—

> If the level of any tobacco additive in the product is in violation of section 1551(c)(2)(A);
>
> If it contains any additive that has been prohibited from use under section 1551(c)(2)(A);

If it contains in whole or in part any filthy, putrid, or decomposed substance; or

If it has been prepared, packed, or held under unsanitary conditions where it may have become contaminated with filth or where it may have been rendered more injurious to health.

Section 1554(a) authorizes the Office of Regulatory Affairs to conduct examinations and investigations for purposes of this subtitle through officers and employees of the Department or through any health officer of a State, territory, or political subdivision. It provides that in the case of tobacco products packed in Puerto Rico or a territory, the Office shall attempt to make inspection at the first point of entry within the U.S., when in the opinion of the Office and with due regard to the enforcement of all of the provisions of this title, the facilities at the Office's disposal will permit of such inspection. As used in this subsection, the term "United States" means the States and the District of Columbia.

Section 1554(b) provides that where a tobacco product sample is collected for analysis, the Center shall, on request, provide a part of such sample for examination or analysis by any person named on the label, or the owner thereof, or the attorney or agent of such persons, except that the Secretary may, by regulation, make reasonable exceptions from, and impose reasonable terms and conditions relating to, the operation of this subsection as the Secretary finds it necessary for the proper administration of this subtitle. Subsection (c) provides that for purposes of enforcement of this title, records of any Federal Government executive branch department or independent establishment shall be open to inspection by any official of the Department of HHS duly authorized by the Office to make such inspection.

Section 1555 provides that any product that contains nicotine but is not a tobacco product as defined in section 1561, shall be considered to be a drug under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act.

Subtitle E of title XV as authorized by the bill contains miscellaneous provisions. Section 1561 defines the following terms as used in this title—

"Center" means the Center for Tobacco Products established under section 1501;

"Interstate Commerce" has the same meaning as in section 201(b) of the Federal Food, Drug, and Cosmetic Act;

"Minor" means any individual under age 18;

"Person" includes individual, partnership, corporation, and association;

"Recipient" means any entity or individual that has received a grant, contract, or cooperative agreement under this title;

"Smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity;

"State" means any State or territory of the U.S., the District of Columbia, and the Commonwealth of Puerto Rico;

"Territory" has the same meaning as in section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act;

"Tobacco additive" means any ingredient that is added to a tobacco product in the process of manufacturing or producing a tobacco product;

"Tobacco product" means cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, snuff, and other products that contains tobacco and is intended for human use.

"Tobacco use" means the use of any tobacco product that is used through smoking, inhalation, or mastication, and such term shall include the use of nasal and oral snuff.

Section 4 of the bill amends the Drug-Free Schools and Communities Act to include tobacco education along with drug and alcohol education under certain provisions of the Act. Section 4(a) amends section 5122(a)(1) of the Drug-Free Schools Act to include State support for tobacco education along with drug and alcohol education under that authority. Subsection (b) amends section 5125(a) to require reference to tobacco education in requirements for local drug and alcohol abuse education and prevention programs. Subsection (c) amends section 5126(a) to include references to tobacco education in requirements for applications for local funds under the Act. Subsection (d) amends section 5132(b) to require the Secretary of Education to provide information for dissemination under section 1527 of the PHS Act and to include reference to tobacco use. Subsection (e) amends section 5141(b)(1) to include tobacco use under the definition of "drug abuse education and prevention" for purposes of the Drug-Free Schools Act.

Section 5 of the bill amends section 5051(i) of the Anti-Drug Abuse Act of 1988 to require that the National Commission on Drug-Free Schools authorized by that Act include references to tobacco education in specific parts of its final report. Under these amendments, recommended criteria in the report for schools to meet to be considered drug-free would include guidelines for a drug education program including anti-tobacco education, referral for treatment for students found to be using tobacco products, and coordinated programs for drug and tobacco use prevention. Recommended criteria would also include a description of assistance required by local school districts to establish smoke-free as well as drug-free schools.

Section 6 of the bill authorizes a program of Incentive Grants to Establish Smoke Free Schools. Subsection (a) authorizes appropriations of $5 million for FY 1991 and such sums as may be necessary for each of FY 1992 and 1993 to enable the Secretary of Education to make incentive grants under this section. Subsection (b) requires a State, to receive a grant under this section, to establish a policy that—

creates smoke-free elementary and secondary school buildings and grounds and school buses;

requires schools to establish smoking areas in which adults only are permitted to smoke, and ensure adequate safeguards exist to protect students from exposure to smoke; and

provides technical assistance to schools and other assistance to implement the provision of this section.

Subsection (c) of section 6 requires a State receiving a grant under this section to use the grant to disseminate materials to school personnel and students, and hold conferences and meetings, concerning the health hazards of tobacco use by students. Subsection (d) requires the Secretary of Education, in consultation with the Secretary of HHS, to promulgate necessary regulations to implement this section. Subsection (e) provides that a State receiving a grant under this section may place restrictions on use of tobacco products in schools in addition to those required in subsection (b). A State receiving funds under this section shall provide assistance under this section only to schools that are subject to State laws described in subsection (b). Subsection (f) provides that no grant may be made under this section unless an application is submitted in such form, manner, and containing such information as the Secretary of Education shall require.

Section 7(a) repeals section 3 of the Comprehensive Smoking Education Act. Section 7(b) repeals sections, 2, 4, 5, and 8 of the Comprehensive Smokeless Tobacco Health Education Act of 1986.

Section 8 requires the Secretary of HHS, not later than one year after the date of enactment of this Act, in consultation with the Secretary of Agriculture, to conduct a study, and prepare and submit to the appropriate Congressional committees, a report on—

the use of pesticides on tobacco and the presence of pesticides in tobacco products;

the effect that the presence of pesticides in tobacco products has on human health; and

whether tolerances should be established for the use of pesticides in tobacco products.

Section 9 provides that nothing in this Act, or any amendments made by this Act, shall be construed to limit, restrict, expand, or otherwise the authority of the Federal Trade Commission.

X. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

[TITLE XV—NATIONAL HEALTH PLANNING AND DEVELOPMENT

[[Repealed by Public Law 99-660]]

TITLE XV—TOBACCO HEALTH AND EDUCATION PROGRAMS

Subtitle A—Center for Tobacco Products

SEC. 1501. ESTABLISHMENT OF CENTER.

(a) In General.—The Secretary shall establish a Center for Tobacco Products that shall be headed by a Director, who shall be appointed by the Secretary.

(b) Functions.—The Secretary, acting through the Director of the Center shall—

(1) educate the public concerning the health consequences of using tobacco products, provide outreach services to youth, and promote cessation of tobacco use through the provision of technical and material assistance to States, workplaces, and the media;

(2) support research efforts concerning patterns of tobacco use and cessation;

(3) provide assistance to States to enhance their efforts to enforce existing State laws concerning the sale of tobacco products to minors within the State;

(4) coordinate the education and research activities of the Federal Government with regard to tobacco products;

(5) document the additives that are contained in tobacco products, determine the additives that represent a health risk, restrict the use of tobacco additives that represent a significant additional health risk to the public, and ensure the disclosure of such information to the public in a manner that assures the protection of proprietary information; and

(6) carry out the programs established under this title.

(c) Contracts.—The Secretary, acting through the Director of the Center, may enter into contracts and cooperative agreements with Federal agencies within and outside of the Public Health Service in the exercise of the functions of the Secretary under this title.

(d) Authorization of Appropriations.—There are authorized to be appropriated to carry out this section $25,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

SEC. 1502. EDUCATIONAL AND RESEARCH ACTIVITIES.

The Secretary, acting through the Director of the Center and in cooperation with non-Federal entities, shall carry out educational and research activities that shall include—

(1) the preparation and distribution of materials to educate the public concerning the health effects of using tobacco products;

(2) the preparation of public service announcements and the preparation and implementation of educational campaigns

(that include paid advertising) to inform specific populations, including youth and the general population, of the health effects of using tobacco products and the opportunities for prevention and cessation of such use;

(3) the provision of information to film makers, broadcast media managers, and others regarding the role of the media in promoting tobacco use;

(4) the conduct of research on patterns of tobacco use, initiation, and cessation, and effective methods for disseminating such information;

(5) the development of plans to effectively provide outreach services to high risk groups and youth with such information; and

(6) the conduct of reviews of the effectiveness of information required to be contained in rotating warning labels on tobacco product packages and the undertaking of research to establish how to improve the effectiveness of such labels.

Subtitle B—Anti-Smoking Programs

CHAPTER 1—PUBLIC INFORMATION CAMPAIGNS

SEC. 1511. GRANTS FOR PUBLIC INFORMATION CAMPAIGNS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center, shall make grants to public or nonprofit private entities, or enter into contracts or cooperative agreements with private entities, to conduct public information campaigns concerning the use of tobacco products.

(b) ACTIVITIES.—Assistance under this chapter shall be used for the development of a public information campaign that may include public service announcements, paid educational messages for print media, public transit advertising, electronic broadcast media, and any other mode of conveying information concerning tobacco products that the Secretary considers appropriate. Such activities shall—

(1) focus on seeking to discourage the initiation of use of tobacco products by youth and nonusers;

(2) encourage cessation of tobacco use by those who currently use tobacco products; and

(3) counter the messages contained in tobacco advertisements that promote tobacco use.

Such activities shall focus on one or more of the specific groups described in subsection (c)(1).

(c) CRITERIA.—The Secretary, acting through the Director of the Center, shall publish the criteria used for awarding grants under this chapter in the Federal Register. Such criteria shall ensure that the applicant—

(1) will conduct activities that educate one or more communities or groups with high prevalences of tobacco use and high health risks from tobacco use, specifically youth, school dropouts, pregnant women, minorities, blue collar workers, and low income individuals;

(2) has a record of high quality campaigns of a comparable type; and

(3) has a record of high quality campaigns that educate the population groups specified in paragraph (1).

(d) PREFERENCE.—

(1) IN GENERAL.—In awarding grants, contracts, or agreements under this chapter, the Secretary shall give a preference to those applicants that will conduct activities that will most likely encompass an audience that includes several of the groups identified in subsection (c)(1).

(2) COMPREHENSIVENESS.—In awarding grants, contracts, or agreements under this chapter, the Secretary shall attempt to distribute such grants, contracts, or agreements so that all groups identified in subsection (c)(1) are reached with diverse media. Single grants, contracts, or agreements shall not require that all groups are reached or that all media must be used.

SEC. 1512. GRANT APPLICATION.

(a) REQUIREMENT.—No grant, contract, or cooperative agreement shall be made or entered into under this chapter unless an application that meets the requirements of subsection (b) has been submitted to, and approved by, the Secretary.

(b) CONTENTS.—An application submitted under subsection (a) shall provide such agreements, assurances, and information, be in such form and submitted in such manner as the Secretary shall prescribe through notice in the Federal Register. Such application shall contain—

(1) a complete description of the plan of the applicant for the development of a public information campaign, including—

(A) an identification of the specific audiences that shall be educated by the campaign, including one or more communities or groups with high prevalences of tobacco use and high health risks from tobacco use, such as youth, school dropouts, minorities, blue collar workers, pregnant women, and low income individuals;

(B) an identification of the media to be used in the campaign and the geographic distribution of the campaign;

(C) a description of plans to test market the campaign with a relevant population group and in a relevant geographic area; and

(D) an assurance that effectiveness criteria will be implemented prior to the completion of the final plan that shall include an evaluation component to measure the overall effectiveness of the campaign; and

(2) a complete description of the kind, amount, distribution, and timing of informational messages and an assurance that the applicant will work with any media organizations or other groups with which such messages are placed to ensure that such organizations or groups will not lower the current frequency of public service announcements.

SEC. 1513. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to make grants or enter into contracts or agreements under this chapter, $50,000,000 for fiscal year 1991, and such sums as may be necessary in each of the fiscal years 1992 and 1993.

CHAPTER 2—MODEL STATE LEADERSHIP INCENTIVE GRANTS FOR ANTI-TOBACCO USE INTERVENTION

SEC. 1515. GRANT PROGRAM.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center, shall designate not less than 10 nor more than 20 States as model States under subsection (b), and shall make grants to each designated model State to assist the State in meeting the costs of improving State leadership concerning activities that—

(1) will prevent the initial use of tobacco products by minors;

(2) will encourage the cessation of the use of tobacco products among the youth and other residents of the State, with particular attention directed towards those individuals and groups who are at high risk and suffer high prevalences of tobacco use, including school dropouts, minorities, low-income individuals, pregnant women and blue collar workers; and

(3) will implement and enforce a prohibition on the sale of tobacco products to minors.

(b) CRITERIA FOR MODEL STATE DESIGNATION.—To be designated as a model State under subsection (a), a State shall—

(1) have in effect a law that prohibits the sale of tobacco products to individuals under the age of 18;

(2) seek to improve the enforcement of the law referred to in paragraph (1);

(3) have in effect a law or regulation that is intended to reduce the use of, or access to, cigarette vending machines by minors who are under the age of 18; and

(4) seek to improve the enforcement of the law or regulation referred to in paragraph (3).

SEC. 1516. APPLICATIONS.

To be eligible to be designated as a model State under section 1515 and receive a grant, a State shall prepare and submit to the Secretary an application that—

(1) includes a designation of a lead agency within the State that will work in conjunction with the Center, and contain assurances that such agency—

(A) has experience in matters that affect the public health;

(B) has expertise regarding the health effects and use of tobacco products;

(C) provides direct services for smoking cessation or referrals for such services;

(D) administers activities intended to prevent the initiation of use of tobacco products by minors who are under the age of 18, and by other individuals;

(E) will have a lead office or division that will have the experience and expertise described in subparagraphs (A) and (B) and will be chiefly responsible for the functions described in subparagraphs (C) and (D); and

(F) will provide personnel sufficient to staff the lead office or division;

(2) provides assurances that as part of a program to improve State enforcement of laws prohibiting the sale of tobacco products to minors the State, will—

(A) establish a mechanism for the reporting of citizen or other complaints to the office or division referred to in paragraph (1)(E) concerning retail establishments that sell tobacco products to minors in violation of State law;

(B) establish a program to make the public aware of the office or division referred to in paragraph (1)(E);

(C) establish a procedure by which the State may make a finding or a presumption that a retail establishment has a pattern or practice of selling tobacco products to minors in violation of State law; and

(D) establish a procedure for the lead State agency to report periodically to the Center regarding the implementation of subparagraphs (A) through (C);

(3) includes a complete description of the type of programs that will be established or assisted by or through the State, and a statement of goals, objectives, and timetables of such programs or activities that are consistent with the purposes of section 1515;

(4) specifies how the State will meet the criteria described in section 1517;

(5) includes copies of the State laws and regulations described in paragraphs (1) and (3) of section 1515(b); and

(6) is in such form, is submitted in such manner, and contains such information as the Secretary shall require, including such other information as the Secretary may by regulation prescribe.

SEC. 1517. GRANT CRITERIA.

The Secretary, acting through the Director of the Center, shall establish criteria for awarding grants under this chapter. Such criteria shall include requirements that the State must provide—

(1) evidence that the State has made efforts to discourage tobacco use among the youth residing in such State;

(2) evidence of the need of the State for the assistance that is requested, as reflected in the prevalence of the use of tobacco within the State, especially among the populations that are described under section 1515(a)(2), and assurances that the State intends to concentrate its efforts on such populations; and

(3) evidence of the need of the State for the assistance that is requested, as reflected in the necessity for the development of statewide expertise in the planning of, and implementation of anti-tobacco use interventions;

(4) evidence of cooperative arrangements that the State has, or will enter into, with other entities that will participate in the activities established or assisted under the grant.

SEC. 1518. ASSISTANCE TO MODEL STATES.

The Secretary, acting through the Director of the Center, shall provide to designated model States, on request—

(1) model printed materials for distribution to retail establishments concerning the health hazards and illegality of the sale of tobacco products to minors;

(2) support for, and assistance in, the planning of meetings, conferences, and conventions to educate retail establishments concerning the health hazards associated with tobacco products, the addictive nature of tobacco products, and State laws that prohibit the sale of tobacco products to minors;

(3) technical assistance in the development of reporting systems to identify specific retail establishments and retail chains that consistently sell tobacco products to minors in violation of State law;

(4) assistance in the development of notification systems to make specific retail establishments aware that such establishments are acting consistently in violation of State law; and

(5) model notices to be distributed to retail establishments concerning the awareness of State authorities and of the Center of the continued sale by the establishment of tobacco products to minors in violation of State law.

SEC. 1519. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There are authorized to be appropriated to make grants under this chapter, $25,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

(b) DISTRIBUTION OF FUNDS.—Funds shall be distributed under this chapter so that no State designated by the Secretary as a model State shall receive more than $2,000,000 for each fiscal year under this section.

CHAPTER 3—EDUCATION TO DECREASE TOBACCO USE IN THE WORKPLACE

SEC. 1521. PURPOSE.

The Secretary, acting through the Center, shall make grants to public and nonprofit entities and enter into contracts and cooperative agreements with private entities (including employer organizations and employer and employee consortia) for educational activities to reduce the incidence of tobacco use among workers with high prevalences of tobacco use. Such grants, contracts, or cooperative agreements shall be used for meeting all or part of the costs of activities that will prevent the initiation, and encourage the cessation, of the use of tobacco products among workers and their families. In making grants and entering into contracts and cooperative agreements, the Secretary shall give priority to applicants that will educate groups with the highest prevalences of tobacco use.

SEC. 1522. ACTIVITIES AND CRITERIA.

(a) ACTIVITIES.—Assistance provided under this chapter shall be used for—

(1) education to promote the cessation of tobacco use among workers who have high prevalences of tobacco use;

(2) information and activities to provide family members of workers with education concerning the health consequences of tobacco use;

(3) training and education to develop the expertise of a health educator or other personnel who will perform the activities described in this subsection for workers and their families; and

(4) the development of audio, visual, or print materials that will facilitate any of the activities described in this subsection when such appropriate audio, visual, or print materials are not otherwise available.

(b) CRITERIA.—The Secretary, acting through the Director of the Center, shall establish criteria for the awarding of grants under this chapter that shall include requirements that the applicant provide to the Secretary, in the application required under section 1523—

(1) evidence of—

(A) the potential for success of the proposed plan of the applicant; and

(B) the existence of any cooperative arrangements with other entities that will participate in the proposed plan;

(2) an agreement that activities to be conducted under the grant will be implemented with the cooperation of the employer; and

(3) any other information as the Secretary shall specify.

SEC. 1523. APPLICATION.

(a) REQUIREMENT.—No grant, contract or cooperative agreement shall be made under this chapter unless an application therefor has been submitted to, and approved by, the Secretary.

(b) CONTENTS.—An application submitted under subsection (a) shall be in such form and submitted in such manner as the Secretary shall prescribe through publication of a notice in the Federal Register. Such application shall contain—

(1) a complete description of the type of educational activities that the applicant intends to carry out with assistance provided under this chapter, including—

(A) a description of the activities that are designed to establish an ongoing anti-tobacco program that may include working cooperatively with existing anti-tobacco programs in the community or State; and

(B) an assurance that activities conducted under subparagraph (A) will demonstrate a concentration of effort to change tobacco use behavior in those groups identified in section 1521 and will include one or more of the activities described in section 1522;

(2) an assurance by the applicant of its ongoing commitments to support the anti-tobacco use activities after the period of the grant, contract, or cooperative agreement has expired;

(3) a description of the manner in which the applicant will meet the criteria specified in section 1522; and

(4) such other information as the Secretary may by regulation prescribe.

SEC. 1524. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to make grants, contracts, or agreements under this chapter, $5,000,000 for each of the fiscal years 1991 through 1993.

CHAPTER 4—INFORMATION REGARDING CIGARETTE SMOKING

SEC. 1526. DEFINITIONS.

As used in this chapter:

(1) COMMITTEE.—The term "Committee" means the committee established under section 1527(c), or the committee established under section 3(b) of the Comprehensive Smoking Education Act (15 U.S.C. 1341(b)) as such section existed before the date of enactment of this section.

(2) UNITED STATES.—The term "United States", when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Island, and the installations of the Armed Forces.

SEC. 1527. SMOKING RESEARCH, EDUCATION, AND INFORMATION IN GENERAL.

(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish and carry out a program to inform the public of the dangers to human health presented by cigarette smoking.

(b) ADMINISTRATION OF PROGRAM.—In carrying out the program established under subsection (a), the Secretary shall—

(1) conduct and support research on the effects of cigarette smoking and of passive smoke on human health and develop materials for informing the public of such effects;

(2) coordinate all research and educational programs and other activities within the Department of Health and Human Services that relate to the effect of cigarette smoking and passive smoke on human health and coordinate, through the Committee, with similar activities of other Federal agencies and of private agencies;

(3) establish and maintain liaison with appropriate private entities, other Federal agencies, and State and local public agencies concerning activities relating to the effect of cigarette smoking and passive smoke on human health;

(4) collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking and passive smoke on human health, and develop standards, criteria, and methodologies to improve information programs related to smoking and health;

(5) compile and make available information on State and local laws relating to the use and consumption of cigarettes;

(6) establish an outreach program to inform individuals under the age of 18 about the health consequences of smoking; and

(7) undertake any other additional information and research activities that the Secretary determines necessary and appropriate to carry out this section.

(c) COMMITTEE.—

(1) ESTABLISHMENT.—To carry out the activities described in paragraphs (2) and (3) of subsection (b), the Secretary shall establish an Interagency Committee on Smoking and Health.

(2) Composition.—The Committee established under paragraph (1) shall be composed of—

(A) the Director of the Center;

(B) members appointed by the Secretary from appropriate institutes and agencies of the Department, that may include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, Health Resources and Services Administration, and the Centers for Disease Control;

(C) one member appointed from each of the Federal Trade Commission, the Department of Education, the Department of Labor, and any other Federal agency designated by the Secretary, the appointment of whom shall be made by the head of the entity from which the member is appointed; and

(D) five members appointed by the Secretary from physicians and scientists who represent private entities involved in informing the public about the health effects of tobacco use and passive smoking.

(3) Chairperson.—The Secretary shall designate the chairperson of the Committee established under paragraph (1).

(4) Expenses.—While away from their homes or regular places of business in the performance of services for the Committee established under paragraph (1), members of such Committee shall be allowed travel expenses, including per diem in lieu of subsistence, in the manner provided by sections 5702 and 5703 of title 5 of the United States Code.

(5) Other information.—The Secretary shall make available to the Committee established under paragraph (1) such staff, information, and other assistance as it may require to carry out its activities effectively.

(d) Report.—Not later than January 1, 1991, and biennially thereafter, the Secretary shall prepare and submit, to the appropriate Committees of Congress, a report that shall contain—

(1) an overview and assessment of Federal activities undertaken to inform the public of the health consequences of smoking and passive smoke and the extent of public knowledge of such consequences;

(2) a description of the activities of the Secretary and the Committee under subsection (a);

(3) information regarding the activities of the private sector taken in to deal with the effects of smoking on health; and

(4) such recommendations as the Secretary may consider appropriate.

SEC. 1528. PUBLIC EDUCATION REGARDING SMOKELESS TOBACCO.

(a) Development.—

(1) In general.—The Secretary, acting through the Director of the Center, shall establish and carry out a program to inform the public of dangers to human health resulting from the use of smokeless tobacco products.

(2) Duties of secretary.—In carrying out the program established under paragraph (1) the Secretary, acting through the Director of the Center, shall—

(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this section;

(C) conduct and support research concerning the effects of the use of smokeless tobacco on health; and

(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

(3) Consultation.—In developing programs, materials, and announcements under paragraph (2), the Secretary shall consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

(b) Assistance.—The Secretary may provide technical assistance and make grants to States—

(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

(2) to assist in the distribution of such programs, materials, and announcements through the States; and

(3) to assist States in enacting laws and regulations to establish 18 as the minimum age for the purchase of smokeless tobacco.

SEC. 1529. REPORTS.

Not later than January 1, 1991, and biennially thereafter, the Secretary shall prepare and submit, to the appropriate Committees of Congress, a report containing—

(1) a description of the effects of health education efforts on the use of smokeless tobacco products;

(2) a description of the use by the public of smokeless tobacco products;

(3) an evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research; and

(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

CHAPTER 5—GENERAL PROVISIONS

SEC. 1535. ADMINISTRATIVE PROVISIONS.

(a) Amount and Method of Payment.—

(1) Amount.—The Secretary shall determine the amount of a grant, contract, or agreement awarded under this subtitle.

(2) Method.—Payments under grants, contracts, or cooperative agreements awarded under this subtitle may be made in advance, on the basis of estimates, or by way of reimbursement, with necessary adjustments because of underpayments or overpayments, and in such installments and on such terms and con-

ditions as the Secretary determines necessary to carry out the purposes of such grants, contracts, or agreements.

(b) Maintenance of Effort.—No grant, contract, or agreement shall be made under this subtitle unless the Secretary determines that there is satisfactory assurance that Federal funds made available under such a grant, contract, or agreement for any period will be so used as to supplement and, to the extent practical, increase the level of State, local, and other non-Federal funds that would, in the absence of such Federal funds, be made available for the program for which the grant, contract, or agreement is to be made and will in no event supplant such State, local and other non-Federal funds.

(c) Supplies, Equipment, and Employee Detail.—

(1) In general.—The Secretary, at the request of a recipient of a grant, contract, or cooperative agreement under this subtitle, may reduce the amount of such a grant, contract, or agreement by—

(A) the fair market value of any supplies or equipment furnished to the recipient by the Secretary;

(B) the amount of pay, allowances, and travel expenses incurred by any officer or employee of the Federal government when such officer or employee has been detailed to the recipient; and

(C) the amount of any other costs incurred in connection with the detail of an officer or employee as described in subparagraph (B);

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience, and at the request, of such recipient and for the purpose of carrying out activities under the grant, contract, or agreement.

(2) Use of amount of reduction.—The amount by which any grant, contract, or agreement awarded under this subtitle is reduced under this subsection shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant, contract, or agreement is based, and such amount shall be considered as part of the grant, contract, or agreement that has been paid to the recipient.

(d) Records.—Each recipient of a grant, contract, or agreement under this subtitle shall keep such records as the Secretary determines appropriate, including records that fully disclose—

(1) the amount and disposition by such recipient of the proceeds of such grant contract, or agreement;

(2) the total cost of the activity for which such grant, contract, or agreement was made;

(3) the amount of the cost of the activity for which such grant, contract, or agreement was made that has been received from other sources; and

(4) such other records as will facilitate an effective audit.

(e) Audit and Examination of Records.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a grant, contract, or cooperative agreement under this subtitle, for the purpose of conducting audits and examinations of such recipient that are pertinent to such grant, contract, or agreement.

Subtitle C—Prohibited Acts, Enforcement, and Additives

CHAPTER 1—PROHIBITED ACTS AND ENFORCEMENT

SEC. 1541. PROHIBITED ACTS.

(a) In General.—The following acts and the causing thereof are prohibited:

(1) Compliance.—The failure of a manufacturer of a tobacco product to comply with section 1551.

(2) Delivery.—The introduction or delivery for introduction into interstate commerce of any tobacco product that is adulterated or misbranded.

(3) Adulteration or misbranding of product in commerce.—The adulteration or misbranding of any tobacco product in interstate commerce.

(4) Receipt.—The receipt in interstate commerce of any tobacco product that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(5) Trade secret.—The using by any person to the advantage of such person, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this title, any information acquired under authority of this title concerning any method or process that as a trade secret is entitled to protection. This paragraph shall not be construed to prohibit disclosure of information to Congress.

(6) Misrepresentation of approval.—The representation or suggestion that an approval of any tobacco product is in effect under this title or any other Federal law or regulation.

(7) Copies of material.—The failure of the manufacturer of a tobacco product to maintain for transmittal, or to transmit, to any individual who makes a written request for information as to such product, true and correct copies of all printed matter that are required to be included in or on any package of a tobacco product.

(8) Reports, records, requirements.—The failure to make reports required, the failure to retain records required, or the failure to meet requirements prescribed, under this title.

(b) Office of Regulatory Affairs.—To carry out this subtitle, the Secretary shall establish within the Public Health Service, or designate an existing entity within such Service as, an Office of Regulatory Affairs. Such office shall coordinate its work with other offices and agencies of the Federal Government.

SEC. 1542. ENFORCEMENT.

(a) In General.—Any person who violates the provisions of this subtitle shall be subject to the penalties described in subsection (b).

(b) Jurisdiction.—The district courts of the United States shall have jurisdiction over violations of section 1541 in the same manner, and may enforce the same and take the same actions, as described under sections 302, 303(a), 303(c)(1), 303(c)(2), 304(a)(1), 304(b), 304(c), 304(d), 304(e), 304(f), 306, and 307 of the Federal Food,

Drug, and Cosmetic Act with respect to violations of section 301 of such Act (20 U.S.C. 331), except that any fines shall be calculated in accordance with the Criminal Fine Improvement Act of 1987, and no showing of interstate commerce shall be required.

(c) CONSTRUCTION.—Nothing in this section shall be construed to preclude any person injured by a violation of this title from seeking redress in an appropriate court to remedy such violation.

SEC. 1543. REGULATIONS.

The Secretary shall have the authority to promulgate regulations to carry out this subtitle.

CHAPTER 2—ADDITIVES; MISBRANDED AND ADULTERATED TOBACCO PRODUCTS

SEC. 1551. TOBACCO ADDITIVES.

(a) REPORTING.—

(1) IN GENERAL.—It shall be unlawful for any person to manufacture, import, or package, any tobacco product brand name unless such person has provided to the Secretary, within the time periods described in paragraph (2), a complete list of—

(A) each tobacco additive used in the manufacture of each tobacco product brand name that such person manufactures, imports, or packages; and

(B) for each such additive, the range of the quantities of such additive used by such person in all tobacco product brand names manufactured, imported, or packaged by such person.

(2) TIME PERIOD FOR REPORTING REQUIREMENT.—

(A) ACTIONS ON DATE OF ENACTMENT.—With respect to any tobacco product brand name manufactured, imported, or packed on the date of enactment of this title, the person manufacturing, importing, or packaging such product brand name shall provide to the Secretary the list required by paragraph (1) not later than 3 months after the date of enactment of this title.

(B) ACTIONS AFTER DATE OF ENACTMENT.—With respect to any tobacco product brand name manufactured, imported, or packed after the date of enactment of this section, the person manufacturing, importing, or packaging such product brand name shall provide to the Secretary the list required by paragraph (1) at least 3 months prior to the date on which such person commences to manufacture, import, or package such product brand name.

(b) ANALYSIS.—Any manufacturer, importer, or purchaser of a tobacco product shall provide the Secretary, on the request of the Secretary, with information regarding the impact of such additives on health.

(c) PUBLIC DISCLOSURE REQUIREMENTS.—

(1) PRESCRIPTION.—Not later than January 1, 1991, the Secretary shall by regulation prescribe requirements for manufacturers to place information on packages of tobacco products or in package inserts that are provided with such products so that the public will be adequately informed of the tobacco additives contained in any brand or variety of tobacco products, except

that spices, flavorings, fragrances, and colorings may be designated as spices, flavorings, fragrances, and colorings without specifically naming each.

(2) REDUCTIONS AND PROHIBITIONS ON USE OF ADDITIVES.—

(A) DETERMINATION.—If the Secretary determines that any tobacco additive in a tobacco product, either by itself or in conjunction with any other additive, significantly increases the risk of the product to human health, the Secretary may require that such levels of the tobacco additive in the tobacco product be reduced or that it be prohibited from use.

(B) BASIS.—

(i) IN GENERAL.—The determination under subparagraph (A) shall be made by regulation.

(ii) COMMENT.—Prior to the issuance of a regulation under clause (i), the Secretary shall provide notice and an opportunity for comment pursuant to section 553 of title 5, United States Code, except that the time for such comment shall not be less than 60 days. The Secretary, in the event that it appears that material facts may be in dispute concerning the proposed regulation, shall provide such appropriate opportunities for the presentation of evidence and for cross-examination of witnesses as the circumstances require either before the Secretary or an officer or employee of the Department designated by the Secretary.

(d) JUDICIAL REVIEW.—Judicial review of a determination under this section shall be governed by and shall be in accordance with section 409(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(g)), except that the requirements of paragraph (3) of such subsection shall not apply.

SEC. 1552. MISBRANDED TOBACCO PRODUCTS.

A tobacco product shall be considered to be misbranded if it is not labeled in accordance with the requirements prescribed by the Secretary under section 1551(c)(1).

SEC. 1553. ADULTERATED TOBACCO PRODUCTS.

A tobacco product shall be considered to be adulterated—

(1) if the level of any tobacco additive contained in the product is in violation of a requirement under section 1551(c)(2)(A);

(2) if it contains any tobacco additive that has been prohibited from use under section 1551(c)(2)(A);

(3) if it contains in whole or in part any filthy, putrid, or decomposed substance; or

(4) if it has been prepared, packed, or held under unsanitary conditions where it may have become contaminated with filth or where it may have been rendered more injurious to health.

SEC. 1554. EXAMINATIONS AND INVESTIGATIONS.

(a) AUTHORITY.—

(1) IN GENERAL.—The Office of Regulatory Affairs is authorized to conduct examinations and investigations for the purposes of this subtitle through officers and employees of the Department or through any health officer or employee of any

State, territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(2) PUERTO RICO AND THE TERRITORIES.—In the case of tobacco products packed in the Commonwealth of Puerto Rico or a territory the Office of Regulatory Affairs shall attempt to make inspection of such products at the first point of entry within the United States, when in the opinion of the Office of Regulatory Affairs and with due regard to the enforcement of all the provisions of this title, the facilities at the disposal of the Office of Regulatory Affairs will permit of such inspection.

(3) DEFINITION.—As used in this subsection the term "United States" means the States and the District of Columbia.

(b) SAMPLES.—Where a sample of a tobacco product is collected for analysis under this subtitle the Center shall, on request, provide a part of such official sample for examination or analysis by any person named on the label of the product, or the owner thereof, or the attorney or agent of such persons, except that the Secretary may, by regulation, make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as the Secretary finds necessary for the proper administration of the provisions of this subtitle.

(c) INSPECTION OF RECORDS.—For purposes of enforcement of this subtitle, records of any department or independent establishment in the executive branch of the Federal government shall be open to inspection by any official of the Department of Health and Human Services duly authorized by the Office of Regulatory Affairs to make such inspection.

SEC. 1555. NONTOBACCO NICOTINE CONTAINING PRODUCTS.

Any product that contains nicotine but that is not a tobacco product as defined in section 1561, shall be considered to be a drug under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)(C)).

Subtitle E—Miscellaneous Provisions

SEC. 1561. DEFINITIONS.

As used in this title:

(1) CENTER.—The term "Center" means the Center for Tobacco Products established under section 1501.

(2) INTERSTATE COMMERCE.—The term "interstate commerce" has the same meaning given such term in section 201(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(b)).

(3) MINOR.—The term "minor" means any individual who is under the age of 18 years.

(4) PERSON.—The term "person" includes individual, partnership, corporation, and association.

(5) RECIPIENT.—The term "recipient" means any entity or individual that has received a grant, contract, or cooperative agreement under this title.

(6) SMOKELESS TOBACCO.—The term "smokeless tobacco" means any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity.

(7) State.—The term "State" means any State or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(8) Territory.—The term "territory" has the same meaning given such term in section 201(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)(2)).

(9) Tobacco additive.—The term "tobacco additive" means any ingredient that is added to a tobacco product in the process of manufacturing or producing a tobacco product.

(10) Tobacco product.—The term "tobacco product" means cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, and snuff, and any other product that contains tobacco and is intended for human use.

(11) Tobacco use.—The term "tobacco use" means the use of any tobacco product that is used through smoking, inhalation, or mastication, and such term shall include the use of nasal and oral snuff.

* * * * * * *

PUBLIC LAW 100-690

ANTI-DRUG ABUSE ACT OF 1988

* * * * * * *

SEC. 5051. NATIONAL COMMISSION ON DRUG-FREE SCHOOLS.

(a) * * *

* * * * * * *

(i) Report of Commission—* * *

* * * * * * *

(A) guidelines for the establishment of a drug education program, *including anti-tobacco education,* for all students in grades kindergarten through 12;

* * * * * * *

(C) referral to treatment for students found to be using drugs, *or tobacco products*; and

(D) coordinated programs for drug *and tobacco* use prevention involving parents, teachers, counselors, local law enforcement personnel, businesses, and community organizations;

* * * * * * *

(3) a description of the assistance required by local school districts to establish drug-free *and smoke-free* schools and the manner in which local, State and Federal Government may provide such assistance; and

* * * * * * *

TITLE 20—UNITED STATES CODE

* * * * * * *

DRUG-FREE SCHOOLS AND COMMUNITIES ACT OF 1986

* * * * * * *

SEC. 3192. STATE PROGRAMS.

(a) IN GENERAL.—

* * * * * * *

(1) local broadly-based programs for drug and alcohol abuse *and tobacco use* prevention, early intervention, rehabilitation referral, and education for all age groups;

* * * * * * *

SEC. 3195. LOCAL DRUG ABUSE EDUCATION AND PREVENTION PROGRAMS.

(a) IN GENERAL.—Any amounts made available to local or intermediate educational agencies or consortia under section 3194(a) of this title shall be used for drug and alcohol abuse *and tobacco use* prevention and education programs and activities, including—

* * * * * * *

(11) public education programs on drug and alcohol **[**abuse**]** *abuse and tobacco use,* including programs utilizing professional and former drug and alcohol abusers;

* * * * * * *

(13) special programs and activities to prevent drug and alcohol abuse *and tobacco use* among student athletes, involving their parents and family in such drug and alcohol abuse *and tobacco use* prevention efforts and using athletic programs and personnel in preventing drug and alcohol abuse *and tobacco use* among all student; and

(14) other programs of drug and alcohol abuse *and tobacco use* education and prevention, consistent with the purposes of this part.

* * * * * * *

SEC. 3196. LOCAL APPLICATIONS.

(a) IN GENERAL.—

(D) describe the extent of the current **[**drug**]** *drug, tobacco* and alcohol problem in the schools of the applicant;

(E) describe the **[**applicant's drug**]** *applicant's drug, tobacco* and alcohol policy, including an explanation of—

(i) the practices and procedures it will enforce to eliminate the sale or use of drugs and alcohol on school premises; **[**and**]**

(ii) how it will convey to students the message that drug use is not permissible; *and*

(iii) how it will discourage use of tobacco products by students;

* * * * * * *

(I) provides assurances that the applicant will coordinate its efforts with appropriate State and local drug and alcohol abuse, health, and law enforcement agencies, in order to effectively **[**conduct drug and abuse**]** *conduct drug and alcohol* *abuse and tobacco use* education, intervention and referral for treatment and rehabilitation for the student population;

* * * * * * *

§ 3212. FEDERAL ACTIVITIES.

* * * * * * *

(b) Federal Drug Abuse Education and Prevention Actvities.—

* * * * * * *

(1) provide information on drug education and prevention to the Secretary of Health and Human Services for dissemination by the clearinghouse for alcohol and drug abuse information established under section 290aa-7 of Title 42 *and for dissemination under section 1527 of the Public Health Service Act;*

(2) facilitate the utilization of appropriate means of communicating to students at all educational levels about the dangers of [drug] *drug and tobacco* use and alcohol abuse, especially involving the participation of entertainment personalities and athletes who are recognizable role models for many young people;

* * * * * * *

§ 3221. DEFINITIONS.

* * * * * * *

(b) Specific Definitions.—For the purposes of this subchapter, the following terms have the following meanings:

(1) The term "drug abuse education and prevention" means prevention, early intervention, rehabilitation referral, and education related to the abuse of [alcohol] *alcohol, the use of tobacco,* and the use and abuse of controlled, illegal, addictive, or harmful substances, including anabolic steroids.

TITLE 15—UNITED STATES CODE

* * * * * * *

[§1341. Smoking, research, education and information

[(a) Establishment of program; Secretary; Functions.—The Secretary of Health and Human Services (hereinafter in this section referred to as the "Secretary") shall establish and carry out a program to inform the public of any dangers to human health presented by cigarette smoking. In carrying out such porogram, the Secretary shall—

[(1) conduct and support research on the effect of cigarette smoking on human health and develop materials for informing the public of such effect;

[(2) coordinate all research and educational programs and other activities within the Department of Health and Human Services (hereinafter in this section referred to as the "Department") which relate to the effect of cigarette smoking on human health and coordinate, through the Interagency Committee on Smoking and Health (established under subsection

(b) of this section), such activities with similar activities of other Federal agencies and of private agencies;

[(3) establish and maintain a liaison with appropriate private entities, other Federal agencies, and State and local public agencies respecting activities relating to the effect of cigarette smoking on human health;

[(4) collect, analyze, and disseminate (through publications, bibliographies, and otherwise) information, studies, and other data relating to the effect of cigarette smoking on human health, and develop standards, criteria, and methodologies for improved information programs related to smoking and health;

[(5) compile and make available information on State and local laws relating to the use and consumption of cigarettes; and

[(6) undertake any other additional information and research activities which the Secretary determines necessary and appropriate to carry out this section.

[(b) Interagency Committee on Smoking and Health; Composition; Chairman; Compensation; Staffing and Other Assistance.—(1) To carry out the activities described in paragraphs (2) and (3) of subsection (a) of this section there is established an Interagency Committee on Smoking and Health. The Committee shall be composed of—

[(A) members appointed by the Secretary from appropriate institutes and agencies of the Department, which may include the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the Health Resources and Services Administration, and the Centers for Disease Control;

[(B) at least one member appointed from the Federal Trade Commission, the Department of Education, the Department of Labor, and any other Federal agency designated by the Secretary, the appointment of whom whall be made by the head of the entity from which the member is appointed; and

[(C) five members by the Secretaray, from physicians and scientists who represent private entities involved in informing the pubic about the health effects of smoking.

The Secretary shall designate the chairman of the Committee.

[(2) While away from their homes or regular places of business in the performance of services for the Committee, members of the Committee shall be allowed travel expenses, including per diem in lieu of subsistence, in the manner provided by sections 5702 and 5703 of Title 5.

[(3) The Secretary shall make available to the Committee such staff, information, and other assistance as it may require to carry out its activities effectively.

[(c) Report to Congress; Contents.—The Secretary shall transmit a report to Congress not later than January 1, 1986, and biennially thereafter which shall contain—

[(1) an overview and assessment of Federal activities undertaken to inform the public of the health consequences of smoking and the extent of public knowledge of such consequences.

[(2) a description of the Secretarys and Committee's activities under subsection (a) of this section.

[(3) information regarding the activities of the private sector taken in response to the effects of smoking on health, and

[(4) such recommendations as the Secretary may consider appropriate.]

* * * * * * *

[§ 4401. Public education

[(a) DEVELOPMENT.—(1) The Secretary of Health and Human Services shall establish and carry out a program to inform the public of any dangers to human health resulting from the use of smokeless tobacco products. In carrying out such program the Secretary shall—

[(A) develop educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco;

[(B) make such programs, materials, and announcements available to States, local governments, school systems, the media, and such other entities as the Secretary determines appropriate to further the purposes of this chapter;

[(C) conduct and support research on the effect of smokeless tobacco and human health; and

[(D) collect, analyze, and disseminate information and studies on smokeless tobacco and health.

[(2) In developing programs, materials, and announcements under paragraph (1) the Secretary shall consult with the Secretary of Education, medical and public health entities, consumer groups, representatives of manufacturers of smokeless tobacco products, and other appropriate entities.

[(b) ASSISTANCE.—The Secretary of Health and Human Services may provide technical assistance and may make grants to States—

[(1) to assist in the development of educational programs and materials and public service announcements respecting the dangers to human health from the use of smokeless tobacco.

[(2) to assist in the distribution of such programs, materials, and announcements throughout the States, and

[(3) to establish 18 as the minimum age for the purchase of smokeless tobacco.]

* * * * * * *

[§ 4403. Ingredient reporting

[(a) IN GENERAL.—(1) Each person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary with—

[(A) a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients; and

[(B) a specification of the quantity of nicotine contained in each such product.

[(2) A person or group of persons required to provide information by this subsection may designate an individual or entity to provide the information required by this subsection.

[(b) REPORT.—(1) At such times as the Secretary considers appropriate, the Secretary shall transmit to the Congress a report, based on the information provided under subsection (a) of this section, respecting—

[(A) a summary of research activities and proposed research activities on the health effects of ingredients added to tobacco in the manufacture of smokeless tobacco products and the findings of such research;

[(B) information pertaining to any such ingredient which in the judgment of the Secretary poses a health risk to users of smokeless tobacco; and

[(C) any other information which the Secretary determines to be in the public interest.

[(2)(A) Any information provided to the Secretary under subsection (a) of this section shall be treated as a trade secret or confidential information subject to section 552(b)(4) of title 5 and shall not be revealed, except as provided in paragraph (1), to any person other than those authorized by the Secretary in carrying out their official duties under this section.

[(B) Subparagraph (A) does not authorize the withholding of information provided under subsection (a) of this section from any duly authorized subcommittee or committee of the Congress. If a subcommittee or committee of the Congress requests the Secretary to provide it such information, the Secretary shall make the information available to the subcommittee or committee and shall, at the same time, notify in writing the person who provided the information of such request.

[(C) The Secretary shall establish written procedures to assure the confidentiality of information provided under subsection (a) of this section. Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent—

[(i) shall take physical possession of the information and, when not in use by any person authorized to have access to such information, shall store it in a locked cabinet or file; and

[(ii) shall maintain a complete record of any person who inspects or uses the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to disclose the information to anyone who is not entitled to have access to the information.]

[§ 4404. Enforcement, regulations, and construction

[(a) ENFORCEMENT.—(1) A violation of section 4402 of this title or the regulations promulgated pursuant to this chapter shall be considered a violation of section 45 of this title.

[(2) Any person who is found to violate any provision of section 4402 or 4403(a) of this title shall be guilty of a mismeanor and shall on conviction thereof be subject to a fine of not more than $10,000.

[(b) REGULATIONS UNDER SECTION 4402 OF THIS TITLE.—(1) Regulations issued by the Federal Trade Commission under section 4402 of this title shall be issued in accordance with section 553 of title 5.

[(2) Not later than 180 days after February 27, 1986, the Federal Trade Commission shall promulgate such regulations as it may require to implement section 4402 of this title.

[(c) CONSTRUCTION.—Nothing in this chapter (other than the requirements of sections 4402 and 4403 of this title) shall be construed to limit, restrict, or expand the authority of the Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of smokeless tobacco products.]

* * * * * * *

[§ 4407. Reports

[(a) SECRETARY'S REPORT.—The Secretary of Health and Human Services shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing—

[(1) a description of the effects of health education efforts on the use of smokeless tobacco products,

[(2) a description of the use by the public of smokeless tobacco products,

[(3) an evaluation of the health effects of smokeless tobacco products and the identification of areas appropriate for further research, and

[(4) such recommendations for legislation and administrative action as the Secretary considers appropriate.

[(b) FTC REPORT.—The Federal Trade Commission shall transmit a report to the Congress not later than January 11, 1987, and biennially thereafter, containing (1) a description of the current sales, advertising, and marketing practices associated with smokeless tobacco products, and (2) such recommendations for legislation and administrative action as it deems appropriate.]

* * * * * * *

TOBACCO EDUCATION AND HEALTH PROTECTION ACT

* * * * * * *

SEC. 6. INCENTIVE GRANTS TO ESTABLISH SMOKE FREE SCHOOLS.

(a) IN GENERAL.—There are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993, to enable the Secretary of Education to make incentive grants to States in accordance with this section.

(b) STATE POLICY.—To receive a grant under this section, a State shall establish a policy that—

(1) creates smoke-free elementary and secondary school buildings and grounds and school buses;

(2) requires schools to establish smoking areas in which adults only are permitted to smoke, and to ensure adequate safeguards exist to protect students from exposure to smoke; and

(3) provides technical assistance to schools and other assistance to implement the provision of this section.

(c) Use of Funds.—A State receiving a grant under subsection (a) shall use such grant to disseminate materials to school personnel and students, and hold conferences and meetings, concerning the health hazards of tobacco use by students.

(d) Regulations.—The Secretary of Education, in consultation with the Secretary of Health and Human Services, shall promulgate regulations necessary to implement this section.

(e) Additional Restrictions.—A State receiving a grant under subsection (a) may place restrictions on the use of tobacco products in schools in addition to the requirements referred to in subsection (b). A State receiving funds under this section shall provide assistance under this section only to schools that are subject to the State laws described in subsection (b).

(f) Application.—No grant may be made under this section unless an application therefor is submitted to the Secretary of Education in such form, in such manner, and containing such information as the Secretary of Education shall require.

SEC. 7. TECHNICAL AMENDMENTS.

(a) Comprehensive Smoking Education Act.—Section 3 of the Comprehensive Smoking Education Act (15 U.S.C. 1341) is repealed.

(b) Comprehensive Smokeless Tobacco Health Education Act of 1986.—Sections 2, 4, 5, and 8 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401, 4403, 4404, and 4407) are repealed.

SEC. 8. STUDY AND REPORT.

(a) Requirement.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Agriculture, shall conduct the study described in subsection (b), and prepare and submit, to the appropriate Committees of Congress, a report concerning the results of such study.

* * * * * * *

○